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INTERAGENCY REGULATORY LIAISON GROUP

Notice of IRLG Work Plans and Public Meetings

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ENVIRONMENTAL PROTECTION AGENCY
Food and Drug Administration
DEPARTMENT OF LABOR
Occupational Safety and Health Administration
[FRL 852-2]

INTERAGENCY REGULATORY LIAISON GROUP
Notice of IRLG Work Plans and Public Meetings

The U.S. Consumer Product Safety Commission, the U.S. Environmental Protection Agency, the Food and Drug Administration, and the Occupational Safety and Health Administration have agreed to work together as the Interagency Regulatory Liaison Group (IRLG): to improve the public health through sharing of information avoiding duplication of effort and developing consistent regulatory policy. This agreement was announced at a joint press conference on August 2, 1977.

On October 11, 1977, the IRLG published in the FEDERAL REGISTER an Interagency Agreement relating to the Regulation of Toxic and Hazardous Substances (42 FR 54856). To implement this agreement, the IRLG established eight work groups to develop common, consistent, or compatible practices in areas of activity common to the four Agencies: (1) compliance and enforcement, (2) education and communications, (3) epidemiology, (4) information exchange, (5) regulatory development, (6) research planning, (7) risk assessment, and (8) testing standards and guidelines.

Following are the provisional work plans of the eight work groups and the schedule of public meetings to discuss these work plans. These plans outline the optimum course of action as it is perceived at this time; nevertheless, the timing and implementation of various tasks within a plan may require reconsideration as priorities and available resources change. They may be revised as new, significant information is obtained.

COMPLIANCE AND ENFORCEMENT WORK PLAN

INTRODUCTION

The Compliance and Enforcement Work Group believes that there are a number of projects which can be undertaken by the cooperating agencies to increase the effectiveness and efficiency of each agency's compliance program. The group's work plan discusses these projects, defines action items which are component parts of the projects, and provides target dates for completing the action items.

The work plan contains projects which deal with the following subjects:

Enforcement Response to Health and Environmental Emergencies,
Personnel Exchange,
Sharing Expertise,
Coordination of Laboratory Facilities and Equipment,
Cooperative Application of Compliance Sanctions,
Compliance Training,
Coordination of Compliance Monitoring and Enforcement Priorities,
Coordination of Inspectional Resources,
Establishing Common or Compatible Investigational Forms.

The regional offices of the agencies are also submitting work plans. Many of these plans contain activities which closely parallel items in the Compliance and Enforcement Work Plan. For this reason, the work group will have to work closely with the regional offices to eliminate duplication of effort and insure successful implementation of each group's compliance related projects.

ENFORCEMENT RESPONSE TO HEALTH AND ENVIRONMENTAL EMERGENCIES

A. *Description of Coordination Activity*

The rapid growth in the chemical industry in recent years has resulted in a corresponding increase in the quantity of hazardous substances that are being processed, transported, used, and disposed of. This increase in activity involving such chemicals increases the threat of accidental release or deliberate use of such substances in the workplace or the environment and in foods, drugs, and other consumer products, in a manner which is or may become harmful to human health or the environment.

In general, such incidents warrant an emergency response when: (1) they cause actual harm to human health or the environment, (2) they pose a substantial risk of harm to human health or the environment, and (3) an immediate and thorough response to the incident may abate, mitigate, or minimize such harm or risk of harm.

B. *Extent of On-Going Activity*

A formal exchange of staff-level contacts has taken place in the past between officials of EPA, FDA, OSHA, CPSC, and USDA. Personnel and offices on the list were designated to be telephone contacts in emergency situations.

Furthermore, interagency coordination has occurred on an incident-by-incident basis where field-level personnel of cooperating agencies have performed specific functions within their areas of expertise to further a joint emergency response effort.

Finally, as part of the IRLG effort, a number of regional work groups are considering the development of coordinated emergency response systems.

C. *Constraints*

The ability of the participating agencies to adequately coordinate their response to emergency incidents is constrained by: (1) the limits of the agencies' statutory authority to respond to emergencies, or to assert appropriate regulatory control in response to the incident, (2) the nature of the technical support available within each agency, and (3) the absence of adequate plans or procedures to direct the activities of the agencies in incidents which overlap the jurisdiction of more than one agency.

D. *Resolution of Constraints*

The constraints which arise from the limits of each agency's statutory authority may be minimized by close cooperation among the participating agencies. Such coordination will assure that the most appropriate regulatory control will be applied in abating or mitigating an incident, regardless of the limits of the regulatory options of the lead agency, and will assure profitable utilization of technical support resources. By careful planning and by adopting detailed interagency procedures for incident response, the programmatic constraints can be effectively resolved.

E. *Action Items*

The Compliance and Enforcement Work Group will coordinate with the various regional groups to insure that field needs are met in the emergency response system. However, the compliance group believes that the basic structure, organization, and function of the system and policy considerations concerning the system should be addressed and resolved at the headquarters level since the system must be capable of meeting possible national or, at least, multi-regional emergencies.

The following action items will be undertaken on a priority basis by the group:

1. *Identify each agency's current emergency response programs and capabilities.* The group will describe current emergency response programs in view of the different statutory authorities of the agencies, will evaluate consistency between programs (e.g., funding, remedies, level of operation), and will identify coordination needs. *Target date for completion: April 1, 1978.*

2. *Designate interagency contact points for emergency response coordination.* The group will develop and exchange the names, addresses, and telephone numbers of general emergency response coordinators at headquarters and in each region, and will establish procedures for notification and coordination of intelligence and technical support. *Target date for completion: April 1, 1978.*

3. *Establish a plan for interagency notification of an emergency incident involving only one agency.* For this action item, the group will develop a

protocol for notification of other agencies with respect to the timing of such notification, information to be supplied, and other criteria. In addition, the unit will establish a mechanism to provide technical support to the lead agency with respect to incident characterization, hazard/damage assessment, and technical evaluation of abatement, mitigation, clean-up, or disposal alternatives. *Target date for completion: June 1, 1978.*

4. *Implement a procedure for interagency response to emergency incidents which involve more than one agency.* The compliance group will establish common criteria for characterizing emergency incidents, will develop a protocol for notification of other agencies with respect to the timing of such notification, information to be supplied, and other factors, and will establish a mechanism to provide technical support to the lead agency with respect to incident characterization, hazard/damage assessment, and technical evaluation of abatement, mitigation, clean-up, or disposal alternatives. In addition, the group will establish interagency coordination procedures, including the coordination of on-scene visits and inspections, collection and analysis of samples, chain of custody, case preparation, and case prosecution. The group also will establish a procedure to review the total array of regulatory tools and statutory remedies to respond to emergency incidents, and will provide a protocol for follow-up analysis of the interagency emergency response performance, and for identifying actions needed to prevent a similar incident in the future. *Target date for completion: November 1, 1978.*

F. *Responsible for Implementation*

A. E. Conroy II, Environmental Protection Agency.

PERSONNEL EXCHANGE

A. *Description of Coordination Activity*

The work group considers a viable personnel exchange program to be an essential element of a successful interagency working agreement—particularly in the compliance and enforcement area. The exchange program should be functional at both the operational and management levels and in both headquarters and regional offices to insure maximum impact. The exchange of personnel, particularly at the management level, might well prove to be the basic foundation which maintains, continues and possibly extends the cooperative work of the agencies.

Establishing a personnel exchange system will create a mechanism for shifting resources from one agency to another to meet short-term work demands. The system will also generate increasing numbers of personnel who have a basic understanding of how other agencies operate, and will result in a cross-fertilization of new ideas. Developing an awareness of the programs of other agencies and exchanging knowledge cannot help but be useful in meeting the objective of increased operating efficiency in the compliance area.

B. *Extent of Existing Activity*

A number of the regional work groups are considering exchange programs.

C. *Constraints*

Possible constraints to an exchange program include: Reluctance of personnel to move between agencies, failure of unions to accept the exchange program, CSC regulations, and the need for training programs.

D. *Resolution of Constraints*

Early in the process, the agency personnel offices will have to determine if unions, CSC regulations or other legal barriers are real obstacles. Reluctance of personnel to shift from one agency to another can be overcome by making sure that the exchange program involves quality employees who are made to feel that the program is an honor and a reward for outstanding job performance.

The one constraint which may create difficulties is in the area of training needed to prepare for an assignment. It must be determined if the cost of the needed training is reasonable compared to the expected benefits. Naturally, the training needed will vary with the type of exchange position involved.

E. *Action Items*

The work group understands that a personnel exchange system may involve areas other than compliance, and that the basic tasks of establishing the system will be given to the personnel offices of the four agencies. However, the Compliance and Enforcement Work Group wishes to be actively involved in the development and implementation of the system to insure that the program will function smoothly in the compliance area—both in headquarters and the field.

The following action items must be accomplished to implement the personnel exchange system:

1. *Determine if valid obstacles exist, and, if so, whether steps can be taken to remedy the problems.* The agency personnel offices will have to undertake this task. *Target date for completion: April 1, 1978.*

2. *Plan the personnel exchange program.* The personnel offices with assistance from the work group will have to evaluate training which may be a necessary part of an exchange program, coordinate with the agency field offices to insure that both headquarters and field objectives are met, identify positions which are viable candidates for exchange, and formalize the system by developing a written program. *Target date for completion: July 1, 1978.*

3. *Implement the exchange system.* The final step for this project is to implement the system, probably on a pilot basis, for a relatively small number of positions in both headquarters and regional offices. *Target date for implementation: August 1, 1978.*

F. *Responsible for Implementation*

Edwin F. Tinsworth, Consumer Product Safety Commission.

SHARING EXPERTISE

A. *Description of Coordination Activity*

Within each agency those individuals who possess technical and scientific expertise will be identified to provide a basis for an interchange of these individuals between the four agencies. In addition, each agency utilizes staff and outside experts who serve as expert witnesses for litigation purposes. Many of these expert witnesses have the knowledge and background which would make them useful to more than one agency. A system will be developed which will identify individuals who can be of use to the various agencies, and which will provide for a sharing and exchange of available expertise among the agencies.

B. *Extent of Existing Activity*

A limited informal exchange of expertise exists on an *ad hoc* basis.

C. *Constraints*

The only major constraint will be finding available time for interagency use of individuals who possess unique expertise.

D. *Resolution of Constraints*

The spirit of interagency cooperation may help to minimize the problem. In addition, as the value of the exchange potential becomes more apparent, the desire to make the system work will increase.

E. *Action Items*

The IRLG has requested that the Education and Communications Work Group take the lead in identifying common scientific and technical areas in which the four agencies operate, and also in developing a list of agency experts in each of those areas. The Compliance and Enforcement Work Group will work closely with the education group and with the regional groups to insure that the needs of both headquarters and regional compliance programs are met.

In addition to the work of the education group, the following action items

must be accomplished in this project area:

1. *Develop a list of expert witnesses and a plan for keeping the list current.* The compliance group will identify expert witnesses currently in use, and also will develop a mechanism for updating the list. *Target date for completion: April 1, 1978.*

2. *Develop and implement a plan to share the expertise of agency personnel.* The Compliance and Enforcement Work Group will work with the education group and regional groups to develop a plan and implementing document which will provide guidelines and criteria for use in sharing and exchanging scientific and technical experts. *Target date for completion and implementation: June 1, 1978.*

F. *Responsible for Implementation*

Edwin F. Tinsworth, Consumer Product Safety Commission.

COORDINATION OF LABORATORY FACILITIES AND EQUIPMENT

A. *Description of Coordination Activity*

This project is primarily concerned with coordinating the use of headquarters controlled laboratory facilities and equipment. However, the group will also work with the regional groups to insure that optimal use is made of field laboratories. The principal areas of concern to the Compliance and Enforcement Work Group are considered to be the following:

1. *The development of common analytical methodologies as they relate to the compliance and enforcement functions.* Work in this area will have to be coordinated with possible similar efforts by the Testing Standards and Guidelines Work Group and the Research Planning Work Group.

2. *The analysis of compliance samples by headquarters laboratories.* Headquarters laboratories are often primarily concerned with methodological development and research. The majority of routine compliance testing is usually done in field laboratories. However, for those compliance tests which are performed by headquarters controlled laboratories, there is an opportunity for interagency cooperation.

3. *The sharing of laboratory facilities and equipment.* This activity has been given considerable emphasis by the regional work groups. In most instances, they have already developed and exchanged inventories of analytical resources and are actively developing plans for implementing a variety of sharing mechanisms on a formal basis. Some *ad hoc* sharing has already occurred. The benefits of such sharing are self-evident; however, several valid constraints have been identified by the regional groups which are equally applicable to the headquarters operations. Of significance to the progress in this plan is the fact that the headquarters units have not developed an inventory of analytical resources. Since this is a necessary first step, it is accorded a high priority in the action plan.

B. *Extent of Existing Activity*

Some formal and *ad hoc* cooperative laboratory operations are occurring in the regions. For example, agency laboratories are participating in a quality control exercise in Region VI. The Quality Control analyses being conducted are for the presence of lead, cadmium, and mercury.

C. *Constraints*

Several constraints are readily apparent which will require some further planning to resolve. Given the day-to-day priorities and programs of each agency, any additional workload will create serious resource management problems. For the most part with respect to the other agencies, analysts are largely unfamiliar with methodologies, laboratory procedures, and types of samples being analyzed. This could hamper cooperative efforts in either the analysis of samples, or in allowing outside analysts to utilize the laboratories of other agencies.

In addition, the regulatory procedures used by each agency are somewhat different with respect to the mechanisms employed for maintaining sample integrity, and finally, analysts performing tests for other agencies may be obliged to testify and/or become involved in lengthy trials if these samples become the subject of litigation.

D. *Resolution of Constraints*

The analytical activities of each cooperating agency need to be surveyed, and common items (e.g., similar products, analytical procedures, or equipment needs) should be identified. These areas could be targeted as good candidates for cooperative efforts. Initial efforts could be reserved for crisis or emergency situations which lend themselves to concessions or ready resolution of funding and resource situations. Cooperation in areas of lesser priority could be worked out later by the affected agencies.

In order to become better acquainted with the various methodologies, procedures, equipment, and types of samples being analyzed by each agency, a personnel exchange system should be instituted between the headquarters laboratories. The regional people are already making plans to accomplish similar exchanges. The Compliance and Enforcement Work Group will consider this point in its personnel exchange project.

The sample handling procedures used by each agency to ensure the integrity of its samples and evidence must be examined to ascertain if a common set of procedures for use by all will suffice. Also, a mechanism for involving analysts in the litigation of samples which they analyzed for another agency could be readily worked out. This is not without precedent in government.

E. *Action Items*

The work group believes that cooperative efforts in the area of methodological development and analytical capability can be of significant benefit.

The group plans to work on the following action items:

1. *Compile an inventory of the analytical capability of the headquarters controlled laboratories of each agency.* The inventory will identify facilities, equipment and technical staff. This action item will be given high priority by the group. *Target date for completion: May 1, 1978.*

2. *Conduct a survey of the analytical activities of each agency to identify common areas in terms of products analyzed, procedures, and equipment which are good candidates for cooperative action.* The regional groups are already performing this activity for field laboratories; the Compliance and Enforcement Work Group will coordinate its work with the regional groups. *Target date for completion: June 1, 1978.*

3. *Devise and implement a management plan to facilitate the referral of samples to other participating agencies.* The initial referrals will be under carefully defined circumstances (e.g., national crisis, severe overload due to a significant unanticipated problem). The plan will include steps needed to insure sample integrity and to allow analysts to testify in trials involving other agencies. *Target date for completion: July 1, 1978.*

4. *Devise and implement a plan to facilitate the interchange of technical personnel between the various headquarters laboratories.* The purpose of this step is to assist the personnel in becoming more familiar with each agency's products, equipment, test methodologies and procedures. The group will consider this matter as part of its personnel exchange project. *Target date for completion: August 1, 1978.*

5. *Devise and implement a plan for the sharing or joint use of laboratory facilities and equipment when such circumstances warrant, and for the development of compatible compliance test methodologies.* Extensive coordination and planning will be required, but the potential benefit makes the item worthwhile. *Target date for completion: September 1, 1978.*

F. *Responsible for Implementation*

John Gomilla, Consumer Product Safety Commission.

Coordination of the Use of Non-Laboratory Facilities and Equipment

NOTE.—The Compliance and Enforcement Work Group originally planned to include a project dealing with coordinating the use of non-laboratory facilities and equipment. However, it became apparent that this type of project primarily impacts on the regional offices and can best be planned at the regional level. For this reason, the group dropped this item as a project. The group will be available to work with the regional work groups in this project if requested to do so.

COOPERATIVE APPLICATION OF COMPLIANCE SANCTIONS

A. *Description of Coordination Activity*

In determining what compliance actions should be taken, an agency must consider whether voluntary correction on the part of a firm is adequate, whether a civil penalty action (where authorized) should be initiated to generate an economic incentive to correct violations, and whether other legal options such as criminal prosecution are warranted. It is important not only to coordinate the application of civil or criminal sanctions, but also, to coordinate the determination that voluntary action is sufficient to correct a situation. In general, it would not be appropriate for one regulatory agency to encourage a voluntary type action or to pursue a civil penalty action, while at the same time a second agency was seeking criminal sanctions against a firm for the same or similar type of violation.

The work group is concerned not only with a situation where one incident results in violations of two or more statutes enforced by two or more regulatory agencies, but also, with a single given firm that, because of its inattentiveness, or lack of control, may violate two or more separate acts enforced by two or more agencies on an ongoing basis. A firm or industry with a poor history of compliance may well be violating more than one statute.

On another level, a regulatory agency may in its programmed operations give attention to an industry or a large segment of an industry with the knowledge that certain violations may be found to exist, and that when identified and substantiated, these violations will result in prescribed regulatory action. This type of activity on an industrywide basis should also be coordinated for more effective application of the law and for better protection of the public.

As an example of the above discussion, the improper disposal of PCB-contaminated waste may involve a violation of the Federal Water Pollution Control Act, the Toxic Substances Control Act, and the Resource Conservation and Recovery Act. Certain pesticide use practices may involve a violation of the Occupational Safety and Health Act and the Federal Insecticide, Fungicide and Rodenticide Act. The work group believes that efficient means should be established whereby the cooperating agencies coordinate their investigation and prosecution of such incidents to achieve maximum impact.

B. *Extent of Existing Activity*

To date, considerable effort has been expended at negotiating memoranda of understanding between participating agencies relating to the cooperative application of compliance sanctions. This effort has culminated in the promulgation of a memorandum of understanding between FDA and EPA. The experience of both agencies under this memorandum of understanding has been highly satisfactory. Other memoranda of understanding exist between the agencies but are not directed to the purpose of this activity.

C. *Constraints*

The unique provisions of the statutes which are enforced by the cooperating agencies will limit the extent to which particular activities may constitute violations of more than one statute. Furthermore, differences in regulatory thrust, statutory intent, or program emphasis will limit the extent to which participating agencies will view an enforcement action prosecuted by another agency as satisfying the mandate of its own regulatory program.

D. *Resolution of Constraints*

The constraints noted above, being statutory in nature, are not subject to easy resolution. Despite these constraints, however, there remain many incidents of joint enforcement jurisdiction which are ripe for cooperative action. Precise provisions of joint agreements may provide for cooperative prosecution of violators by means of the most efficient enforcement remedies of the statutes providing regulatory jurisdiction.

E. *Action Items*

The Compliance and Enforcement Work Group will work with the regional groups and the General Counsels of the cooperating agencies to develop viable plans for obtaining maximum benefits from voluntary industry actions and enforcement proceedings.

The following action items will be undertaken:

1. *Catalog the general jurisdiction of each statute enforced by each agency.* A draft paper covering areas of jurisdiction has already been developed. *Target date for completion: April 1, 1978.*

2. *Identify activities which may constitute a violation of statutes enforced by different agencies.* This action item will further define the possible areas of cooperation. *Target date for completion: April 1, 1978.*

3. *Establish a Compliance Sanction Ad Hoc Committee which will catalog the relevant existing and planned memoranda of understanding, determine where new memoranda of understanding are needed, and meet routinely to implement the intent of this project and, in particular the next action item.* The committee may consist of both work group members and other agency personnel. *Target date to establish the committee and catalog the memoranda of understanding: June 1, 1978.*

4. *Establish and implement memoranda of understanding between participating agencies regarding the prosecution of cases involving violations of statutes enforced by separate agencies.* This will likely be a long-term activity with a variety of memoranda of understanding being generated over time. *Target date for the first memorandum of understanding: September 1, 1978.*

F. *Responsible for Implementation*

Thomas W. Brown, Food and Drug Administration.

COMPLIANCE TRAINING

A. *Description of Coordination Activities*

The Compliance and Enforcement Work Group views compliance training as a necessary element in the cooperative compliance efforts of the agencies. The necessary training falls into two categories: (1) training of agency personnel, including both orientation and crossover training, and (2) joint industry seminars. The work group plans to restrict itself to technical training. Non-technical educational programs (e.g., a general seminar presented to a college student body) will be handled by the Education and Communications Work Group.

Orientation training would provide basic compliance information concerning the authorities and practices of each agency to both headquarters and regional personnel. Such training would be particularly important for field investigators and their supervisors and for personnel who may be involved in an exchange program. The work group views compliance orientation training as something which can be done relatively quickly, and can provide the basic knowledge needed for investigators to be able to detect obvious violations of other agencies' laws so that the matters can be referred for proper follow-up. In addition, this type of training may be sufficient to support a personnel exchange program for some types of positions.

Crossover training would be much more detailed than orientation training. The concept of crossover training

is a program which would enable investigators of one agency to either perform basic inspectional work of other agencies or, at a minimum, to conduct joint inspections with personnel from other agencies. Staff other than investigators might also receive crossover training to support the personnel exchange project. It is anticipated that crossover training is a longer term proposal both in the planning and implementation phases.

The work group also believes that joint industry seminars could have a very positive impact on both the industry and the agencies. Such seminars could be used to present a target audience with the basic information needed to comply with the legal requirements of all four agencies. Such an approach would present a uniform front to the industry, would prevent the industry from playing one agency off against another, and would probably be very helpful to small businesses which cannot afford to attend multiple seminars.

From an agency viewpoint, the use of joint seminars would generate a better understanding of issues, would foster new ideas on how to approach problems, and would maintain the cooperative spirit which is the foundation of the current agreement.

The work group realizes that many of the regional groups are considering training projects. The compliance group will work closely with the regional groups to insure that headquarters and field efforts are coordinated.

B. *Extent of Existing Activity*

Some informal joint industry seminars are held but little crossover or orientation training is performed between agencies. A number of regional groups are planning or have implemented some joint training efforts.

C. *Constraints*

There are no apparent constraints for orientation training. Crossover training is much more difficult and its usefulness depends on to what extent the agencies decide to use joint and crossover inspections, and to what extent the personnel exchange program is utilized. Resources may be a problem. Two apparent constraints for industry seminars are the necessity for the agencies to mesh priorities as to which industries need the seminars, and for the agencies to work out a clear presentation of their respective programs.

D. *Resolution of Constraints*

If joint and crossover inspections are determined to be feasible and are implemented on a nationwide basis and if the exchange program extends to positions which require detailed training, the agencies will have to allocate resources and time to develop a worthwhile compliance training program. As far as industry seminars are concerned, the priority problem can be handled by targeting industries for seminars which are on each agency's priority list.

E. *Action Items and Implementation Plans*

Working closely with the regional groups, the compliance group will address the following action items:

1. *Establish a Compliance Training Ad Hoc Committee and plan the orientation training.* A committee consisting of members of the Compliance and Enforcement Work Group and probably other agency personnel will be established; the committee will plan implementation training. *Target date to establish the committee and plan the training: May 1, 1978.*

2. *Implement orientation training.* The start of implementation training can be tied to the initiation of the personnel exchange program. *Target date for implementation: August 1, 1978.*

3. *Explore ways to implement crossover training, and utilize the training committee to finalize plans.* Crossover training will require more detailed analysis and planning. *Target date for finalizing plans: September 1, 1978.*

4. *Implement crossover training.* The extent of crossover training will depend on the type of position involved, but even the less detailed training will take a great deal of time to properly implement. *Target date for implementation: December 1, 1978.*

5. *Plan industry seminars.* The compliance group will work closely with the regional groups to develop both industry seminars, covering general compliance issues, and, assuming needs can be meshed, industry seminars covering more specific regulatory concerns. *Target date for completion of plans: July 1, 1978.*

6. *Implement the seminars.* The group believes that the seminars should be implemented on a regional basis, and therefore coordination with the regions will be essential to get the seminars started. *Target date for implementation: October 1, 1978.*

F. *Responsible for Implementation*

Taylor M. Quinn, Food and Drug Administration.

Coordination of Compliance-Monitoring and Enforcement Priorities

A. *Description of Coordination Activity*

The work group believes that a sound basis exists for the coordination of compliance monitoring and enforcement priorities. Compliance monitoring refers to document reviews, inspections, sample collections, sample analyses and other surveillance activities conducted to determine whether regulatory standards are being observed. Compliance monitoring occurs in accordance with a routine surveillance strategy or in response to particular suspected violations. Enforcement refers to case preparation, case prosecution and other prosecutorial activities undertaken in response to a detected violation.

Frequently, more than one of the four cooperating agencies conduct compliance monitoring at the same facility or establishment. Subject to the surveillance demands of the various regulatory programs, the agencies may coordinate compliance monitoring priorities by (1) fostering the establishment of common criteria for planning program activities, (2) exchanging and coordinating work plans to direct field activities, and (3) coordinating inspection, sampling, analytical and prosecutorial activities. The ability of the participating agencies to establish consistent compliance monitoring and enforcement priorities will greatly impact the extent to which efforts at cooperative inspections can result in efficient utilization of resources.

B. *Extent of Existing Activity*

At present, there is only minimal direct coordination of criteria for setting compliance monitoring and enforcement priorities. Some common elements may be found in the criteria which are applied by the cooperating agencies. These arise, however, more directly from the common requirements of the legislation enforced by the cooperating agencies than from deliberate program coordination. Little collaboration has occurred regarding the extent to which considerations of health risk, for example, will direct the compliance monitoring and enforcement priorities of the participating agencies; nor have the agencies explored in detail bounds which should be placed upon the health-effects outlined or the manner in which a joint concern for health-effects would impact the choice of surveillance targets or enforcement prosecutions. While each agency's work plans for current field activities are readily available to the participating agencies, they have rarely been exchanged.

C. *Constraints*

The unique provisions of the statutes which are enforced by the cooperating agencies may limit the extent to which joint program management criteria may be established. Program coordination is most feasible where different agencies perform compliance monitoring in the same categories of facilities or establishments. Furthermore, the diverse nature of the regulatory problems which have been established pursuant to various legislation will limit the extent to which more than one agency will perform compliance monitoring activities at the same facilities or establishments.

D. *Resolution of Constraints*

The constraints noted above, being statutory in nature, are not subject to easy resolutions. Despite these constraints, however, there remain many areas of joint regulatory coverage which are ripe for cooperative action. Cooperative action may arise in those areas of joint regulatory concern for which there is no statutory impediment and where the management of each participating agency agrees, as appropriate, to: (1) establish common criteria for setting priorities, (2) establish consistent bounds on such criteria, and (3) apply such criteria in a uniform manner to the surveillance and enforcement activities undertaken by their field staff.

E. *Action Items*

The Compliance and Enforcement Work Group views its role in this project as being the unit responsible for providing guidelines, criteria and policy statements which can be incorporated in each agency's work planning efforts for implementation by the regional offices.

The following action items will be pursued by the group:

1. *Establish, as appropriate, common criteria for setting priorities for compliance monitoring and enforcement activities.* The work group will identify existing criteria for establishing compliance monitoring and enforcement priorities utilized by the participating agencies, and will identify surveillance programs for which criteria are similar, or can be made sufficiently similar, to warrant implementation of cooperative compliance monitoring programs. *Target date for completion: September 1, 1978.*

2. *Exchange existing work plans and coordinate the preparation of future work plans to direct field activities of surveillance programs.* The group will exchange current operating plans for field-level surveillance activities, will participate in the identification and prioritization of surveillance targets, and will coordinate the preparation of work plans to accomplish the appropriate level of surveillance of various compliance monitoring targets. *Target date for completion: September 1, 1978.*

3. *Implement to the maximum extent practicable, the coordination of compliance monitoring and enforcement activities.* This action item is actually a project, in itself. As such, it is discussed in the following section of the work plan.

F. *Responsible for Implementation*

A. E. Conroy II, Environmental Protection Agency.

COORDINATION OF INSPECTIONAL RESOURCES

A. *Description of Coordination Activity*

The Compliance and Enforcement Work Group has identified three levels of interagency cooperation which can be undertaken to coordinate compliance monitoring and inspectional activities: (1) referral inspections, (2) joint inspections, and (3) crossover inspections.

Referral inspections are inspections conducted by one agency which result in the referral of a violation to another agency for follow-up inspection by the other agency. The development of checklists containing the substantive requirements of each agency's regulations, and the execution of orientation training of field personnel of each participating agency are prerequisites to the implementation of a referral inspection program.

Joint inspections are concurrent, multi-agency inspections of a single facility. Such inspections would enable the participating agencies to share background information in preparation for the inspection. Furthermore, such inspections would minimize the number of separate inspections to which the owner/manager of the facility must submit. Joint inspections are feasible only with respect to those facilities which are subject to the requirements of more than one agency and only when the inspection of such a facility is consistent with the compliance monitoring priorities of more than one agency.

Crossover inspections are inspections conducted by personnel of one agency who are qualified and empowered to carry out inspections and perhaps also to cite violations under the authority of statutes administered by another agency. The execution of extensive training regarding the substantive requirements of the regulations of each agency and unique inspectional procedures of each agency must be accomplished to implement crossover inspections. Furthermore, the formal delegation of each agency's inspectional authorities and the "commissioning" of appropriate field personnel of each agency to conduct inspections on behalf of other agencies are prerequisites to the implementation of a crossover inspection program. The expected benefit of this level of interagency cooperation is the development of an inspectional cadre which is trained and authorized to execute the compliance monitoring programs of all four agencies. Such a cadre, for example, would be useful for a remote geographic area, where an investigator of one agency could perform compliance work for several agencies.

The goals of these coordinated functions are to: (1) achieve better compliance information sharing at the field level between agencies; (2) achieve a more efficient coverage of the industries jointly regulated by the agencies, and a more effective use of limited field resources; and (3) lessen the burden upon the regulated industries imposed by repeated federal compliance inspections.

B. *Extent of Existing Activity*

At the present time there is little formal coordination established between the agencies. There are a number of limited and informal program agreements between the agencies. For example, EPA and FDA have executed a formal memorandum of understanding which establishes a referral inspection program in the enforcement of pesticide tolerances on foodstuffs and misuse of pesticides.

The regional work groups are actively beginning to plan and implement efforts in this project area.

C. *Constraints*

A number of factors constrain the extent to which any coordination of inspectional activities may be undertaken. These constraints include limited areas of joint regulatory attention, inconsistent compliance monitoring and enforcement priorities, and statutory limitations upon the ability to delegate authority or commission personnel of other agencies to conduct compliance inspections. In addition, the need to perform increasingly detailed and sophisticated training of field personnel of participating agencies and management problems involved in coordinating inspectors' schedules are constraints which will impact the ability to coordinate work in this area.

D. *Resolution of Constraints*

If referral, joint and crossover inspections are to be conducted on a nationwide basis, the agencies will have to allocate the resources and time to resolve the programmatic and logistical constraints noted in the above section.

Each agency must perceive that the efficiencies resulting from these coordinated inspections will justify the substantial front-end investment in training and supervisory coordination that will be required to resolve the management constraints. The constraints which arise from the scope of each agency's regulatory programs, and limitations in the ability to delegate authority or commission personnel of other agencies must be identified and minimized, if they cannot be resolved.

E. *Action Items*

A number of the regional work groups are planning or have implemented activities in this area. The Compliance and Enforcement Work Group will coordinate its efforts with the regional groups. Some local coordinated inspectional activity will occur before the compliance group finalizes national guidelines and procedures in this area.

The following action items will be undertaken by the compliance group:

1. *Identify areas of joint regulatory attention.* The group will assemble a list of the types of facilities subject to regulation, will prepare a summary list of the categories of requirements imposed upon each type of facility, and will conduct an analysis of the level of cooperative inspection (referral, joint, crossover) which is appropriate for each type of facility. *Target date for completion: May 1, 1978.*

2. *Implement a referral inspection program.* The work group will develop and distribute checklists of requirements regulated by each agency, and a list of easily-detected violations, and will develop orientation training as needed to alert field personnel of each agency to violations that they may encounter. In addition, the unit will work with the regional groups to develop and exchange a list of field-level referral contacts. Finally, the groups will implement referrals to appropriate agencies by the field-level exchange of information. *Target date for starting referral inspections on a nationwide basis: September 1, 1978.*

3. *Implement a joint inspection program.* The work group will identify regulatory candidates for joint inspection (by one or more participating agencies) by reviewing targets of joint regulatory interest, common compliance monitoring priorities, and common management interest in inspecting the same facilities. The group will also prepare an interagency schedule for joint inspections, and the regions will then begin to execute joint inspections on a nationwide basis. *Target date for starting nationwide joint inspection programs: October 1, 1978.*

4. *Implement a crossover inspection program.* The compliance group will evaluate the feasibility of crossover inspections by requesting the agency General Counsels to assist the group in conducting a statute-by-statute analysis of any limitations on the ability to delegate authority or commission personnel of other agencies to conduct compliance inspections. The group will develop appropriate training regarding the substantive requirements of all regulations monitored by crossover inspection, and any procedural requirements of the statutes being enforced. In addition, the unit will coordinate compliance monitoring priorities and allocation of field-level personnel to achieve maximum coverage from the inspectional activities of participating agencies. Finally, the compliance and regional groups will launch a limited pilot program of cross over inspections. *Target date to start pilot program: January 1, 1979.*

F. *Responsible for Implementation*

A. E. Conroy II, Environmental Protection Agency.

ESTABLISHING COMMON OR COMPATIBLE INVESTIGATIONAL FORMS

A. *Description of Coordination Activity*

The work group plans to study the feasibility of developing common or compatible investigational forms to facilitate the exchange of information and data. Forms which will be studied include inspection forms, sample collection forms and consumer complaint forms. If the group finds that some forms can be made compatible or identical, and if the group determines that the potential benefit is worthwhile, the project will be expanded to include the development of the forms.

In addition, the group will develop a checklist which can be used by investigators of each agency to identify possible violations of laws enforced by other agencies. This checklist will be used for referral inspection purposes.

B. *Extent of Existing Activity*

A number of the regional groups are actively involved in this project area, and are considering the use of common forms on a pilot basis. In addition, EPA and OSHA have had preliminary discussions in this area.

C. *Constraints*

Problems may arise due to differences in operating procedures and work practices, differing legal and regulatory requirements, and differing requirements for data collection. In addition, OSHA reports that alteration of forms may be considered a change in work practices and may require, in some cases, discussion with the approval by the union bargaining agent for the field employees,

D. *Resolution of Constraints*

Assuming that the development of common forms is determined to be feasible, possible union obstacles will have to be addressed and resolved through negotiation.

E. *Action Items*

The Compliance and Enforcement Work Group will coordinate its efforts on this project with the regional groups. Early in the process, it must be determined if the use of common forms is feasible, and, if so, if the benefits are worthwhile, particularly for field activities.

The following action items will be pursued:

1. *Evaluate the feasibility of developing common or compatible forms and identify candidate forms.* The work group will study the issues of feasibility, will identify potential candidate forms, and will work with the regional groups to insure that any forms which are deemed to be good candidates will meet the needs of the field offices. *Target date for completion: April 1, 1978.*

2. *Develop and implement common or compatible forms.* Assuming that some forms are determined to be candidates for consolidation into a common format, the group will work with other agency personnel to develop and begin the use of the common or compatible forms (perhaps on a pilot basis). The group anticipates that the forms will be developed as part of an ongoing process. *Target date for developing and beginning use of the first form: August 1, 1978.*

3. *Develop a checklist for referral inspections.* The group will develop a checklist for use by inspectors in identifying violations of the laws administered by each agency. The checklist will be used as part of the referral inspection program. *Target date for developing checklist: August 1, 1978.*

F. *Responsible for Implementation*

Roger Clark, Occupational Safety and Health Administration.

PROJECT SUMMARY SHEET

Action items and target dates

Project: Enforcement Response to Health and Environmental Emergencies

1. Identify each agency's current emergency response programs and capabilities—April 1, 1978.

2. Designate interagency contact points for emergency response coordination—April 1, 1978.

3. Establish a plan for interagency notification of an emergency incident involving only one agency—June 1, 1978.

4. Implement a procedure for interagency response to emergency incidents which involve more than one agency—November 1, 1978.

Project: Personnel Exchange

1. Determine if valid obstacles exist, and, if so, whether steps can be taken to remedy the problems—April 1, 1978.

2. Plan the personnel exchange program—July 1, 1978.

3. Implement the exchange system—August 1, 1978.

Project: Sharing Expertise

1. Develop a list of expert witnesses and a plan for keeping the list current—April 1, 1978.

2. Develop and implement a plan to share the expertise of agency personnel—June 1, 1978.

Project: Coordination of Laboratory Facilities and Equipment

1. Compile an inventory of the analytical capability of the headquarters controlled laboratories of each agency—May 1, 1978.

2. Conduct a survey of the analytical activities of each agency to identify those common areas in terms of products analyzed, procedures and equipment which are good candidates for cooperative action—June 1, 1978.

3. Devise and implement a plan to facilitate the referral of samples to

other participating agencies—July 1, 1978.

4. Devise and implement a plan to facilitate the interchange of technical personnel between the various headquarters laboratories—August 1, 1978.

5. Devise and implement a plan for the sharing or joint use of laboratory facilities, and for the development of compatible compliance test methodologies—September 1, 1978.

Project: Cooperative Application of Compliance Sanctions

1. Catalog the general jurisdiction of each statute enforced by each agency—April 1, 1978.

2. Identify activities which may constitute a violation of statutes enforced by different agencies—April 1, 1978.

3. Establish a Compliance Sanction Ad Hoc Committee which will catalog the relevant existing and planned memoranda of understanding, determine where new memoranda of understanding are needed and meet routinely to implement the intent of this project and, in particular, the next action item—June 1, 1978.

4. Establish and implement memoranda of understanding between participating agencies regarding the prosecution of cases involving violations of statutes enforced by separate agencies—September 1, 1978.

Project: Compliance Training

1. Establish a Compliance Training Ad Hoc Committee and plan the orientation training—May 1, 1978.

2. Implement orientation training—August 1, 1978.

3. Explore ways to implement crossover training, and utilize the training committee to finalize plans—September 1, 1978.

4. Implement crossover training—December 1, 1978.

5. Plan industry seminars—July 1, 1978.

6. Implement the seminars—October 1, 1978.

Project: Coordination of Compliance Monitoring and Enforcement Priorities

1. Establish, as appropriate, common criteria for setting priorities for compliance monitoring and enforcement activities—September 1, 1978.

2. Exchange existing work plans and coordinate the preparation of future work plans to direct field activities of surveillance programs—September 1, 1978.

3. Implement to the maximum extent possible, the coordination of compliance monitoring and enforcement activities—See next project.

Project: Coordination of Inspectional Resources

1. Identify areas of joint regulatory attention—May 1, 1978.

2. Implement a referral inspectional program—September 1, 1978.

3. Implement a joint inspection program—October 1, 1978.

4. Implement a crossover inspection program—January 1, 1979.

Project: Establishing Common or Compatible Investigational Forms

1. Evaluate the feasibility of developing common or compatible forms and identify candidate forms—April 1, 1978.

2. Develop and implement common or compatible forms—August 1, 1978.

3. Develop a checklist for referral inspections—August 1, 1978.

DECEMBER 9, 1977.

MR. EDWIN F. TINSWORTH,
Chairman, Compliance and Enforcement Work Group.

EDUCATION AND COMMUNICATIONS WORK PLAN

EDUCATION

I. *Objectives*

A. To plan, develop, and evaluate a coordinated education program directed toward consumers;

B. To plan and develop a coordinated external training program for key consumer representatives who can produce a multiplier effect;

C. To recommend guidelines for promoting the implementation of an external coordinated education and training program;

D. To recommend a coordinated communication system for reaching the target populations to whom these education and training (external) programs are to be directed; and

E. To assess the effectiveness of labelling as an educational tool and a preventative strategy.

II. *Scope of work*

The above objectives will focus on:

A. Consumer and worker health and safety;

B. Toxic substances;

C. External training;

D. Labelling of toxic substances.

III. *Description of coordinated activities*

A. *Publications Booklet.* Each agency has printed materials geared toward common audiences that can be used to raise their awareness level and knowledge level about health and safety. We propose to develop a *Health and Safety Publications Booklet for Consumers.* Such a document would have some annotated listings of health and safety publications and audiovisual materials of interest to educators, consumers in the home environment and employees in the work place. It will address such concerns as consumer product safety, foods, drugs, toxic chemical substances, and other areas relating to health and safety protection.

The publications booklet will include the following:

1. The working title and cover legend of the booklet is to be: "It's For You To Know . . . A listing of information materials you can obtain about dangerous chemicals in your environment, home and workplace."

2. The objective of this publication is to help the public learn what information materials are available to them from CPSC, EPA, FDA and OSHA concerning the law, specific chemicals, protection/prevention, etc.; how to obtain that information, etc. Along with being a handy catalog, it is intended to let the citizen (esp. teachers, health personnel and others who frequently request such material) judge by comparison which are the "correct" materials for a particular purpose from among many available.

Key elements will be:

(a) Intro . . . table of contents . . . "how to use this booklet" etc.

(b) General publications available from four agencies and how to order.

(c) Selected technical publications and how to order; where to go for other specific technical information.

(d) Slide shows, filmstrips, A/V shows, etc.; how to order films; etc.

3. Production Schedule:

(a) Approve scope and plan for project, 2/1/78.

(b) Approve overall project; Agency Heads, 2/15/78.

(c) Draft and layout finished, 3/31/78.

(d) Approvals/suggested changes thru four agencies, 4/15/78.

(e) Out for typesetting, 4/30/78.

(f) Mechanicals finished, 5/15/78.

(g) To printing, 5/16/78.

(h) Finished, first printing, in-hand, 7/15/78.

4. Distribution will be via several routes: selected agency mailing lists, and upon individual request through the Consumer Information Center.

The booklet will be developed on a contract. Anticipated quantity is 225,000-750,000 copies.

Lead Agency: Joint—EPA (Mike Scott) and CPSC (Elizabeth Johnson).

B. *Education and Training (external) Curriculum Guide for Briefings and Workshops.* This is intended to be a two-sectional document to be used by regional and area offices of each of the four agencies:

1. *Section I*—A coordinated comprehensive guide to be used in the conduct of briefings with key national, regional, and state consumer-oriented organizations relative to the structure, functions, and process for implementation of the interagency agreement. This section would increase consistency of information presented and assist regional directors in being certain that major elements of the structure, the planning, and the projects being developed are accurately presented.

2. *Section II*—A general education and training curriculum guide for the

conduct of health and safety workshops. It would be developed to encourage consistency, but it would also encourage flexibility. A model would be pilot tested and then replicated for national implementation. The conduct of cooperative annual regional education workshops by regional and area offices of the four principal regulatory agencies charged with protecting the public and the environment from adverse effects of toxic and hazardous substances would be a meaningful and significant step. These cooperative annual workshops are intended to attract local representatives of consumer-oriented organizations who have a multiplier effect, an established constituency, and established network of communications, and who are willing to assist us in our educational goal of an "informed safety minded consumer".

Lead Agency: CPSC (Elizabeth Johnson).

C. *Development of a Generic Health and Safety Curriculum Activity Guide for Schools.* The development, promotion, and distribution of a generic health and safety curriculum activities guide for elementary, middle, and senior high schools would greatly enrich the present school curriculum while at the same time provide a natural blend into existing goals and curriculae. The implementation of this guide in schools would raise the level of health and safety awareness among the nation's most vulnerable population—our children. We therefore, propose the development of a *Generic Health and Safety Curriculum Activities Guide for Schools.*

Lead Agency: CPSC (Elizabeth Johnson).

D. *Effective Labelling as an Educational Tool and Preventive Strategy.*

Hypothesis statement: Effective labelling is an educational tool that communicates a basic message requiring the reader or user to make a decision about his behavior.

The following tasks are identified:

1. A review of the state of the art of labelling of toxic substances through or by CPSC, EPA, FDA, and OSHA.

2. Analyze the findings of the state of the art.

3. Establish a clear, specific coordinated strategy for labelling that can be jointly accepted and implemented by the above four agencies and the appropriate regulatory personnel.

The criteria for establishing labelling as a preventive strategy and an educational tool must include the following:

It is understandable to the user/reader;

It has panels that contain directions and treatment to the user that is attractive and attention drawing to the user so that the message will want to be read;

The print is legible (enlarged print size, type form, color contrast, etc.);

Directions that are short, concise, and in *simple* language;

The label has been pre-tested for readability, comprehension, clarity, and elimination of confusion.

Lead Agency: CPSC (Elizabeth Johnson).

ADDENDUM—EDUCATION/COMMUNICATIONS TASK FORCE

Development of a Generic Health and Safety Curriculum Activity Guide for Schools.—Purpose and Description—The purpose of this Curriculum Activities Guide is to provide a resource manual for teachers of elementary, middle, and senior high school grades in teaching basic health and safety content to their students. The content would focus on those categories of products over which the four agencies have jurisdiction.

The guide would have, as a minimum, the following:

Introduction; purpose and how the guide can be used; interdisciplinary approaches and opportunities; how the content fits into existing curricula; basic concepts to be taught; objectives (behavioral and learning); background information for the teacher; information about the four agencies; suggested activities; laws protecting the health and safety of consumers; pre and post tests; knowledge and behavior inventories; and resource material listings.

Some of the health and safety content categories would include:

Home safety; school safety; safety and health in the work place; environmental health and safety; and food, drug, and cosmetic safety.

Distribution—The Curriculum Activities Guide would be distributed (with an accompanying letter) to the 10,000 or more public school curriculum specialists across the country; to school supervisors of consumer education, home economics, industrial education, distributive education, social sciences, health-physical-and safety education. The Guide would, also, be distributed to parochial schools. If the quantities are sufficient, one guide should be placed in each school in the country.

Accompanying each Guide would be a "franked" self mailer—two fold which would have about 5-7 evaluative questions. This would serve as a preliminary evaluation feedback.

COMMUNICATIONS

I. BROCHURES/PRINT MATERIALS

A. General Information Booklet on Toxic Substances and the IRLG.

Scope and implementation of project are listed below:

1. "The Chemical Threat"—working title.

2. The objective of this publication is to help the public understand what the government is doing to protect the citizen from the dangers of certain chemicals and advise on self protection.

The key areas in the booklet will be:

(a) What these chemicals are that we're concerned with.

(b) Where they are and why—in products, the workplace, the environment.

(c) How people can protect themselves from the dangers of these chemicals; how they can be protected.

(d) The law: Food, Drug and Cosmetic Act, Occupational Safety and Health Act, Toxic Substances Control Act, PPA, HSA, etc.

(e) The agencies that carry out those laws—who they are, what they do—their activities—especially those related closely to the daily life of citizens, workers, consumers.

(f) What the Government does not do in the area of toxic substances; why.

(g) How the citizen can work with the Government to correct a problem—which agency is the right one for which problem.

(h) The IRLG—what it is all about and why—what it is not.

(i) Directory: Organizational tables; chief/key personnel, addresses, phones; how to get to the right office; what to do when you can't seem to get an answer to your question.

3. Production schedule: (a) Approve scope and plan of project, work group, October 14, 1977; (b) approve overall project, agency heads, October 31, 1977; (c) draft finished ready for approval, March 1, 1978; (d) approvals/suggested changes—through all 4 agencies, March 15, 1978; (e) final draft with changes approved, agency heads, March 29, 1978; (f) out for typesetting, April 12, 1978; (g) mechanicals finished, May 2, 1978; (h) to GPO (w/letter from IRLG heads asking special service), May 9, 1978; and (i) finished first printing (500,000 copies) in hand, June 5, 1978.

4. Distribution for the publication would be via several routes. Copies will be furnished to each agency for mailing to their own mailing lists. Copies will be printed and shipped to cover bulk requests by the agencies' constituencies (e.g.: labor unions, consumer groups, women's groups, agriculture associations, trade associations, press and media, environmental organizations, etc.) for redistribution to their memberships. Agencies will also be supplied with quantities for headquarters and field offices for the numerous kind of requests out of general inventory.

Finally, arrangements will be made to distribute in response to continuing general inquiries via the Consumer Information Center in Colorado. This is a service already used by 3 of the IRLG agencies to distribute much of their public information material, and so coordination and cooperation will be both simplified as well as desirable. Also, mention will be made of the brochure in our PSA.

5. Lead Agency—EPA (Mike Scott).

B. Guidelines for Emphasizing Interagency Cooperation in Agency Publications.

On November 7, 1977, a memorandum was sent to the Directors of Communications/Public Affairs/Education of CPSC, EPA, FDA, and OSHA requesting that they use and distribute, as appropriate, in headquarters and regional offices, the below listed Guidelines, as approved by the IRLG, in their publications.

Guidelines for Emphasizing Interagency Cooperation

The Heads of the FDA, EPA, CPSC, and OSHA have been emphasizing the need for their agencies to cooperate more closely and to avoid duplication of effort in regulatory and scientific activities.

On September 26, the agency heads signed an agreement setting forth eight areas of cooperation. A copy of this agreement is attached.

As part of the new spirit of cooperation among the agencies, the Work Group on Education and Communications urges all four agencies to emphasize in their publications and other public materials the cooperative effort.

Specifically, the Work Group urges:

That the interagency agreement be the subject of a story in internal newsletters produced by the four agencies.

That the agreement be the subject of a longer story in any other periodical publications issued by the four agencies, such as magazines.

That appropriate press emphasis be given to the effort by the press offices of the agencies.

There is also a need for publications and other public materials to give proper emphasis to the occasional overlapping authority and responsibilities of the four agencies. The public is often confused about which agency is responsible for particular areas, and about overlapping authority.

For example, if a brochure is being published about toxic substances by EPA, the brochure should mention that other agencies also are active in enforcing this new law, and give how the authority and responsibilities are distributed.

If an FDA brochure is being written about prescription drugs, mention should be made of the safety packaging required under a law enforced by CPSC.

If OSHA is regulating a chemical in the workplace, FDA in foods and drugs, EPA in pesticides and CPSC in consumer products, publications should make clear how the agencies interact and where their responsibilities lie.

Publications also should refer to other agencies for additional information about a subject. This might be done in the form of "For further information about this subject, write to—."

Lead Agency: FDA (Wayne Pines).

II. FILMS/AUDIO-VISUAL MATERIALS

A. Production of a Fourteen (14) Minute Color Film (16 mm).

1. *Scope.*—The film would stress two main points: (1) the need for people to take responsibility for their own self-protection from products, at home and at work, and (2) the need for reading labels as a means of self-protection. The film would also point out the general responsibilities of each of the four agencies, and stress the agencies' limitations in providing absolute protection from hazards or deception.

2. *Dissemination.*—Modern Talking Pictures, a commercial firm, would receive 300 copies for bookings. FDA consumer affairs officers would use the film as an integral part of their consumer education programs; OSHA, EPA, and CPSC would have the films available through their headquarters and regional offices. There would be a major effort to book the film for showing on local and national television, through letters to stations signed by the four agency heads. There also should be a major effort to encourage schools to use the film in their consumer education projects, and each of the four agencies would incorporate the film into its consumer education program.

3. *Project schedule.*—A contract could be signed within three months after a dollar commitment is made. It would then take three months for writing and production of the film.

4. *Lead agency.*—FDA (Wayne Pines).

III. HEARINGS AND PUBLIC MEETINGS CALENDAR

This project is intended to keep each agency informed of rulemaking hearings and public meetings regarding toxic substances that are of interest to the four agencies. Also, this will serve as a way to hold joint meetings for agency heads and personnel, and can also reduce duplication in efforts.

A calendar will be published during the third week of each month which will list relevant hearings and meetings for the following month. The calendar will consist of: the subject of the meeting, the time and location, the "lead" agency, and a contact. An initial calendar will include events up to six months in advance, and will be updated, as necessary.

EPA will be responsible for compiling this calendar based upon submission of upcoming events from the counterparts of the other agencies. The submissions will be due about the middle of each month. EPA will forward the completed calendar to the counterparts, who will be responsible for distribution within the agencies and the public. We also will suggest that the recipients of the calendar encourage joint coordination or sponsorship of hearings and meetings.

Lead Agency: EPA (Larry O'Neill). (Sample calendar format is attached.)

"MODEL CALENDAR"

DRAFT

JANUARY 1978 --- PUBLIC MEETINGS AND HEARINGS CALENDAR FOR OSHA, EPA, CPSC AND FDA

The calendar, issued monthly, lists public meetings and hearings regarding toxic substance issues involving the four agencies. Additions, corrections or comments should be addressed to EPA, Public Awareness Office (A-107), 401 M Street, SW., Washington, D.C. 20460, ATTN: Larry O'Neill, phone: 202/755-0344.

SUBJECT	TIME, LOCATION	LEAD AGENCY	CONTACT

IV. INTERAGENCY DIRECTORY

A. A Directory has been established which includes:

1. The Interagency Regulatory Liaison Group, whose eight members act as surrogates for the four Principals or Agency Heads in coordinating and managing the execution of the Interagency Agreement;

2. The Eight Work Groups established under the Interagency Agreement. One IRLG member serves as liaison between one work group and the IRLG;

3. Other Key Contact Personnel within each agency headquarters offices, including:

(a) Regulatory Alert System contact persons who notify the other three agencies of planned or impending regulatory action.

(b) Correspondence/Referral (mail) Contacts who will answer referral inquiries within the agencies and will expedite replies to the consumer.

4. Field Offices: CPSC area offices, EPA, FDA, and OSHA regional offices.

This Interagency Directory is being issued to the Directors of Communications/Public Affairs/Education of CPSC, EPA, FDA and OSHA for distribution, as appropriate, in headquarters and regional offices. The Directory will be periodically revised.

Lead Agency: CPSC (Nancy Marcellino).

V. CORRESPONDENCE/REFERRAL (MAIL)

Background: Letters and complaints received by us represent the first contact the consumer has had with the various agencies. We are commited to providing the consumer with accurate and speedy responses. This initial contact between agency and consumer is a valuable one and must be considered as an opportunity to interact with the consumer in a positive and professional manner.

We are aware that each agency has its own system for recording and processing consumer inquiries and complaints. However, we feel that the use of uniform guidelines, within the four agencies for recording and answering misdirected mail and complaints, will expedite replies to the consumer and simplify collation of information among the agencies.

A. Guidelines for Information Referral

1. At point of opening, misdirected mail should be routed daily to the interagency "contact" person, as listed in the interagency directory. The "contact" person will:

(a) Keep a daily log to record the following information (See sample log sheet attached):

(1) name of consumer,
(2) date inquiry is received,
(3) agency to receive referral,
(4) date referral is received,
(5) date referral is answered,
(6) "Red flag" letters of a more serious nature, i.e., potential health hazards.

(b) Compile and mail monthly reports to other agencies (from daily log) for comparison with those received from the other agencies.

(c) Misdirected mail should receive preference because of the time lost in getting the letter to the appropriate agency.

(d) A prepared letter, explaining why the incoming correspondence was referred to another agency, should be sent to the consumer the same day as the inquiry is received. This letter could also describe, in brief terms, the responsibility of the agency referring the letter.

2. Telephone referrals:

(a) Where appropriate, telephone consumer directly and give the telephone number of the proper agency.

(b) Consumer telephone calls should be referred to the appropriate agency and the consumer urged to call back if he does not receive a satisfactory reply.

3. Publications:

(a) IRLG agencies should advise each other when putting items in their publications in order that the appropriate agency can gear up for a possible increase in inquiries.

Lead Agency: FDA (Alex Grant).

IRLG LETTER REFERRAL LOG

DRAFT

Name of Consumer	Received From				Referred to			
	Date of Letter	Agency	Date	Red Flag	Agency	Date	Red Flag	Date of Reply

VI. PRESS RELEASE/PRESS CONFERENCE COORDINATION

A. This plan is intended to ensure that each agency is informed of news events of interest and that each agency has a fair and equal chance to participate in the announcement.

Each work group news contact will be responsible for identifying as far in advance as possible those rules, enforcement actions, or other events that involve other IRLG agencies and that warrant a news release, conference or other coverage.

The news contact at the agency that is the "lead" for the action will notify her or his counterparts and consult on how to best make the announcement. The "lead" news contact will be mainly responsible for drafting the news release or other material and, in the case of a news conference, for making physical arrangements. The "lead" should feel free to call upon his IRLG colleagues for help in this work.

The "lead" will also be responsible for obtaining clearance of the material from all the agencies involved and will strive to incorporate his views in the final work. The "lead" will attend to reproduction of the material for the event. His counterparts will assist in press notification.

Because of the short lead-times and unpredictable nature of many news happenings, this system has to be regarded as fluid and subject to change as circumstances dictate. It will work only if each of the agency's news contacts cooperate with each other.

B. The press officer from each agency, as listed in our interagency directory, assigned to the above coordination is listed below:

Consumer Product Safety Commission, Susan Smirnoff Charles, 202-634-7780.
Environmental Protection Agency, Marlin Fitzwater, 202-755-0344.
Food and Drug Administration, John T. Walden. 202-443-4177; Wayne Pines, 202-443-3285; Nancy Glick, 202-245-1144.
Occupational Safety and Health Administration, Jim Foster, 202-523-8151.

Lead Agency: EPA (Larry O'Neill).

VII. PUBLIC SERVICE ANNOUNCEMENTS (TV, RADIO, PRINT)

A. Production and distribution of a series of jointly sponsored radio, television and print messages.

1. Scope: The PSA campaign would focus on a broad generic hazard that is under the purview of all the agencies, such as pesticides. The materials would present basic warning information and explain that as a consumer or a worker he or she has a right to expect and require protection, but the joint responsibility belongs to industry as well as to the consumer. In general, the campaign would be designed to give simple basic information that would raise the level of awareness and concern. It should also provide a response mechanism so that a listener or viewer can write or call for more information, such as the joint booklet on toxic substances.

2. Implementation and Distribution: The Work Group should initiate contact with the Advertising Council as well as other production and distribution firms. The Work Group may be able to produce the material independently of the Advertising Council—(probably with some savings) and then offer it to them for approval and distribution. There are several other distribution agencies available. Basically, copies of the radio and television spots could be made available to every broadcast outlet in the country. The materials would be distributed to all major magazines and major newspapers as well as specialized publications such as union newspapers or local consumer newsletters. Copies of the materials would also be made available to the regional offices of the four agencies for local distribution and use.

3. Project Schedule: Six months from the time of commitment of funds, a campaign could be in distribution.

4. Lead Agency—OSHA (Frank Greer).

MR. KENNETH R. RASHID,
Chairman, Education and Communications Work Group.

DECEMBER 1, 1977.

EPIDEMIOLOGY WORK PLAN

GOAL A—IDENTIFICATION OF EPIDEMIOLOGY PROGRAMS AND EPIDEMIOLOGY RESOURCE PERSONNEL

The severe limitation in personnel in epidemiology within the four agencies as well as nationally requires that these scarce resources be utilized as effectively as possible. Sharing information on programs and personnel should provide assurance that there is no unnecessary duplication of effort, that high priority needs are receiving support, and that individuals engaged in these studies are aware of the talents that they can draw upon in other agencies for assistance in their own projects.

Task 1.—Identification of Epidemiology Resource Personnel—The Epidemiology Work Group has decided that a listing of personnel will be most useful if it identifies both those individuals who have received academic training in epidemiology and those whose work directly contributes to epidemiological projects. Therefore, the list will classify individuals in epidemiology under the following operational categories: (1) individuals with academic credentials in epidemiology, (2) individuals with experience and/or training in the application of epidemiological methods, (3) support individuals for epidemiological research and application (biostatisticians, statisticians, information specialists, etc.)

The report identifying personnel of this agenda item is expected on January 31, 1978.

Task 2.—Identification of Epidemiology Programs—This task will begin with output on epidemiology programs from the Research Planning Work Group. This material will be amended if necessary to meet criteria established by the Epidemiology Work Group. Epidemiologists and related scientists in the four agencies will be queried for additional programs.

The target date for completion of this task is February 28.

GOAL B—GUIDELINES FOR EPIDEMIOLOGICAL STUDIES

An increasing number of "epidemiological studies" have been submitted to various government agencies involved in the regulatory process over the past several years. Many of these studies have provided a factual basis for regulation. However, others have led to lengthy debate due to inadequate design, inadequate data, and inappropriate analyses, often delaying public health actions and sometimes resulting in inconsistent decisions by different agencies having overlapping or joint interests. Furthermore, such inadequacies have too often led to un-

necessary or inappropriate expenditure of scarce resources; i.e., time of professional staff and money, to "redo" the research. To more readily facilitate the objective conduct and evaluation of epidemiologic studies which may be used for regulatory decisionmaking, the Epidemiology Work Group has determined that it is necessary to develop and promulgate guidelines for such epidemiologic studies. While it is not intended that a standard model be developed against which epidemiologists would mold their research, we believe it is necessary to develop minimal criteria by which submitted studies can be objectively evaluated.

Task 1.—Guidelines Development, Announcement and Promulgation—The Epidemiology Work Group will develop draft guidelines for announcement in the FEDERAL REGISTER for public comment and, after consideration of comments, for promulgation as formal guidelines.

The milestones for this task are as follows:

Develop draft guidelines—May 30, 1978.

Announcement in the FEDERAL REGISTER—September 30, 1978.

Promulgation of formal guidelines in the FEDERAL REGISTER—March 31, 1979.

Task 2.—Epidemiologic Methods Research and Documentation—Simultaneous to the development of draft guidelines, the Epidemiology Work Group will undertake:

A. An evaluation of selected published studies with regard to their design, analysis and conclusions, and

B. Research in epidemiologic methods concerning the critical effects of demographic, confounding and study variables.

Each of these subtasks will provide for background documentation and support the promulgation of draft guidelines.

The milestones for this task are as follows:

Subtask A—Six months after allocation of resources.

Subtask B—Twelve months after allocation of resources.

GOAL C—IDENTIFICATION OF LEGAL AUTHORITIES AND REQUIREMENTS FOR EPIDEMIOLOGIC STUDIES

Increasing evidence documents that medical, industrial hygiene, engineering control, and monitoring records are often not retained after a few years by corporations, hospitals, and others. This adversely impacts on our ability to identify heretofore unrecognized or unacknowledged health hazards associated with chemicals and processes. Evidence also documents corporate opposition to the access of existing records for health evaluation purposes, even in the presence of highly suggestive data supporting a health hazard. Currently, regulations prescribed under most existing legislation are addressing record retention only after the recognition of a health hazard. However, records must be retained and studied in order to identify health hazards *de novo*.

Several regulatory agencies routinely require safety testing of chemicals in animals. There is much less use of existing authorities to require industry to carry out epidemiological studies using its own records. Such epidemiological studies would identify adverse health effects which failed to be documented in animal tests. The extent of federal legal authorities to set standards for industry-conducted epidemiological studies, and to enter industry in order to carry out government studies, needs further exploration. Furthermore, once a chemical is found to be safe in animal studies, the extent to which human testing for effects that would not show up in animal tests needs tc be explored from both a scientific and ethical perspective.

Task 1.—Identification of Existing Authorities—The Work Group has already requested General Counsels in each agency to survey the current legal authorities within each agency to require retention, collection, collation, and disclosure of data pertinent to human disease potential. This survey also has addressed the authorities each agency has to share and transfer right-of-entry for such data. We are also investigating existing authorities to require industry to carry out epidemiological studies, our authorities to set minimum quality standards for such industry studies, and our authorities pertaining to industry-conducted human testing.

Proposed timetable: March 15, 1978.

Task 2.—Need for Additional Agreements for Authorities—After analyzing the responses from all General Counsels, the Work Group will make recommendations for:

A. Immediate action in the form of prescribed regulation under existing legislative authorities. Proposed timetable: Continuing effort.

B. Future actions such as interagency agreements and proposed legislative changes. Proposed timetable: Continuing effort.

GOAL D—DEFINING DATA BASES OF INTEREST

The Epidemiology Work Group discussed a variety of data bases and problems associated with the use of such data sources. The data bases include those at NCI, various cancer registers, Professional Activity Studies, Bureau of Census data, Social Security Administration data, data from the National Center for Health Statistics, and others. Several subcommittees were formed to explore the following problem areas associated with the use of such data bases. These problems include:

1. The right to access and the method of access.

2. The methods to be used to challenge the denial of the use of a particular data base.

3. Resources needed to access particular data bases.

Subcommittees have been established to explore the data bases of the Social Security Administration, Professional Activity Studies, the National Center for Health Statistics and the Center for Disease Control. The first report from these subcommittees is expected on February 28, 1978. Additional target dates will be set as specific problems and opportunities are identified.

DR. ROBERT D. VERHALEN,
Chairman,
Epidemiology Work Group.

JANUARY 23, 1978.

INFORMATION EXCHANGE WORK PLAN

I. SUMMARY

The IRLG suggested that common requirements of the four regulatory agencies be identified, current systems surveyed, and new or modified systems developed in order to promote effective information exchange.

A recently completed study by MITRE sponsored by CEQ, EPA, and NLM has identified these requirements, surveyed existing systems, and proposed a loosely-coupled network of new systems and modified current systems. This proposed Chemical Substances Information Network may be viewed as an overall blueprint for developing effective information exchange among the four agencies.

The Information Exchange Group has identified six projects which are consistent with the MITRE study. These projects are appropriate for coordinated action by the four agencies, and would facilitate information exchange considerably.

Four of the six projects provide for coordination of on-going activities presently performed independently by the four agencies. The remaining two projects call for feasibility studies and eventual development of new automated information systems to serve the four agencies.

To successfully overcome the inherent inertia of these on-going activities, these coordination projects will require strong support and attention from the administrators to ensure full cooperation from all key agency personnel in affected organizations. These four projects may briefly be described as:

A. Use of common identification codes for related information among all four agencies. This would apply to

codes for specific chemicals, establishment sites, products, and uses. These codes would be applied to both new and existing systems of interest to the four agencies, unless a written cost/benefit analysis, approved at an appropriate level, demonstrates that it is not reasonable to do so.

B. Development of common procedures for safeguarding confidential information. Policies should be consistent so that confidential information can be exchanged among any or all of the four agencies without loss of security.

C. Joint monograph (criteria document) planning and production. Monographs could be designed to include requirements of all four agencies, and procurement simplified through master task order type contracts.

D. Development of criteria for coordination of reporting requirements. To the extent permitted by differing agency laws and missions, certain types of data submission from regulated industries could be made uniform among the four agencies, leading to enhanced data sharing capability and to a reduction in the reporting burden placed upon industry.

The two recommended system projects would begin with feasibility studies and lead to development of the following interagency systems:

E. Regulated Chemicals System—contains information on standards and regulations which have been proposed or promulgated concerning individual chemical substances or classes of chemicals; and,

F. Chronic Testing Support System—contains results of long-term chronic toxicity monitoring studies, and provides a strong analytic capability.

In addition, a seventh project has been identified to support the work of the Information Exchange Work Group to provide continuing management of work plan activities and to continue to assess agencies' information needs and propose answers to these needs.

The remainder of this action plan contains a perspective section which provides some highlighting of the MITRE Study and demonstrates its appropriateness for consideration by the four agencies; a section on the four coordination projects; a section describing the two systems projects which should be entered into jointly by the four agencies; a recommendations section; and a table showing examples of possible future projects. The Information Exchange Work Group recommends that the four Agency Heads approve the seven projects and provide resources sufficient to implement them.

II. PERSPECTIVE

The IRLG suggested that common requirements of the four agencies be identified, current systems surveyed, and new or modified systems developed in order to promote effective information exchange.

A recently completed study by MITRE sponsored by CEQ, EPA, and NLM has identified these requirements. The study concerned itself with the following regulatory agency functions and data categories needed to support those functions:

Functions of Regulatory Agencies

(1) Hazard Identification/Prioritization; (2) Hazard Analysis; (3) Research/Development; (4) Decision Package Development (Criteria Documents); (5) Monitoring/Analysis; (6) Preparation of Regulations and Guidelines; and (7) Enforcement/Compliance.

Data Categories Needed to Support Those Functions

(1) Substance Indentification; (2) Production Aspects; (3) Marketing; (4) Exposure; (5) Epidemiology; (6) Biological; (7) Environmental; (8) Standards/Regulations; and (9) Managerial/Administrative.

This study, completed June 1977, also includes a survey and evaluation of current systems, and proposes a coordinated plan for developing new systems and modifying old ones so they will more effectively meet regulatory agency needs. This proposed Chemical Substances Information Network may be viewed as an overall blueprint for developing effective information exchanges among the four agencies.

It is not a monolithic super-system however, nor even a series of systems electronically tied together. Rather it is a set of individual components which, when viewed together, can be used to effectively meet information needs of agencies involved in regulatory chemicals.

The ten core system components of the proposed network are:

(1) Chemical Data Base Directory; (2) Chemical Structure/Nomenclature System; (3) TSCA Chemical Data System (Proprietary); (4) TSCA Chemical Data Systems (Public); (5) TSCA Reports Management System; (6) Toxicology Data System; (7) Chronic Testing Support System; (8) Bibliographic Literature Scanning System; (9) Laboratory Animal Data System; and (10) Regulated Chemical Standards System.

CEQ has funded a feasibility study to further evaluate the requirements, implementation alternatives, costs, and benefits of the first two of these components of the proposed network. All or parts of several such system components exist or are contemplated outside the IRLG. However, two system components appear appropriate for IRLG development, and are discussed below in some detail.

III. COORDINATION PROJECTS

The Information Exchange Work Group has identified four projects which provide for coordination of ongoing activities presently performed independently by the four agencies.

These four projects are discussed separately below.

A. Common Identification Codes

The first coordination project provides for the use of common identification codes for related information among all four agencies.

This would apply to codes for specific chemicals, establishment sites, products, and uses. These codes would be applied both to new as well as existing information systems which would be commonly useful among the four agencies, unless a written cost/benefit analysis demonstrates it is not reasonable to do so.

There should be a common policy and implementation plan developed in all four agencies that requires that the Chemical Abstracts Service (CAS) registry number be associated with each chemical in all agency files. Once a chemical has been identified by one means or another, and its CAS number determined, access to all available information in all other files can be obtained by means of the common CAS number.

The CAS number could be placed within existing files or could be maintained in a separate table with an appropriate link into the existing file. Once this association has been established, the list of CAS numbers in the file should be provided to NLM for entry into CHEMLINE, and to EPA for entry into the EPA/NIH Chemical Information System.

There should be a common policy and implementation plan developed which requires the association of a common site-specific establishment identification code for all establishment information in all agency files. This would permit a user to identify all available information in all agency files for any given establishment. The Dun and Bradstreet number appears to be most readily adapted to this purpose, but further study is being made so that a final choice can be made by the four agencies in concert.

There should be a common policy and implementation plan developed which requires the association of a common product identification code for all product related information in all agency files. This would permit the location of specific product information in various files among the four agencies. FDA and CPSC have a strong interest in this area.

There should be a common policy and implementation plan developed which requires the association of a common hierarchical use-code for chemicals in all agency files. This would apply to uses of chemicals as determined by processors, formulators, distributors, and retailers. This would permit the location of information by

use-code in all agency files, and specific chemical to be identified.

B. Confidential Information

The second coordination project would provide for the development of common procedures for handling and securing confidential information.

There should be a common policy and implementation plan developed for the safeguarding of confidential information. Whenever confidential information is shared between agencies (as permitted by law) common procedures would minimize the possibility of error due to unfamiliarity with the other agency's procedures. This should also give industry more confidence in our collective ability to share confidential information without undue risk.

C. Monograph Planning and Production

The third coordination project provides for planning and procurement of monographs (criteria documents) and similar documents.

Monographs are substantial literature analyses of a specific topic, most typically on the toxicity of a chemical or class of chemicals.

Three of the four agencies (EPA, CPSC, FDA) issue contracts to commercial firms for monograph production. OSHA's monographs are developed by NIOSH. The cost of these monographs ranges from about $20,000 in contract costs upwards. In addition to contract costs, agencies contribute considerable resources in expert review of drafts, negotiation with and guidance of contractors, etc.

Increased coordination among the four agencies would result in substantial savings and better monographs for all. As an example, the incremental costs of adding environmental data to an occupational health monograph are considerably less than the cost of preparing a monograph on the same topic in order to assess its environmental impact.

D. Reporting Requirements

The fourth project provides for the coordination of reporting requirements in the four agencies.

These agencies impose requirements upon industry to supply data on chemicals they manufacture, import, use, or sell. Each agency's requirements are developed and implemented independently of the others, except for limited coordination provided by the Office of Management and Budget under the provisions of the Federal Reports Act. The General Accounting Office has similar duties relative to the Consumer Product Safety Commission.

The goal of this project is greater uniformity in industry submissions of data, leading to enhanced data sharing capability and to a reduction in the reporting burden placed upon industry.

The scope of this project is all voluntary or mandatory requirements for reporting or recordkeeping under the cognizance of one or more of the four agencies, where the subject of the report is a chemical substance. All such requirements are in the scope, whether or not there is any concern with the toxic effects of the subject chemicals.

Work will initially focus on requirements of the four agencies, and may then be expanded to cover requirements of other agencies in the Federal government, with the cooperation of the Office of Management and Budget.

IV. SYSTEM DEVELOPMENT PROJECTS

Two of the ten core system components of the Chemical Substances Information Network appear appropriate for development by the four agencies: a Regulated Chemicals System and a Chronic Testing Support System. This development process should begin with a feasibility study to sharpen the definition of requirements, identify implementation alternatives, perform cost/benefit analyses, and prepare recommendations for management review. Full cognizance will be taken of on-going activities in the public and private sectors which may be used as a base for the proposed systems.

E. Regulated Chemicals System

The Regulated Chemicals System would provide the user with information on standards which have been proposed or promulgated concerning individual chemical substances or classes of chemicals. The system would incorporate occupational standards, transportation, packaging, and labeling requirements, threshold levels, and various procedural regulations which impose industrial reporting requirements with respect to individual chemical substances or classes of substances. State, Federal, and international standards are all included. The system would be implemented on a data base management system that is publically available, thereby providing information to manufacturers and processors as to their respective responsibilities under various legislative authorities. Government agencies and international organizations require this system to maintain awareness of proposed and promulgated standards in order to minimize the development of conflicting standards.

F. Chronic Testing Support System

The Chronic Testing Support System would provide a software capability and storage and retrieval module for the results of long term chronic toxicity monitoring studies. The system may be used by government agencies in the conduct of long term toxicological studies (e.g., cancer bioassays conducted by NCI), by government agencies who need to review the studies (e.g., by EPA in carrying out its responsibilities under TSCA and FEPCA to review test results), or by industry when required to conduct chronic tests in response to government regulation. The system design would incorporate the requirements of the Carcinogenesis Bioassay Program of the National Cancer Institute and the integrated laboratory support capability required by the National Center for Toxicological Research. It would support private, independent agency, or industry files with access and update privileges limited to approved users. The goal of the system would be to provide a computer utility for collection, monitoring, evaluating, and reporting of bioassay information. The system would permit collection of data on chemicals and chemical preparations, the experimental procedures and test environment, the observation data and complete pathology reports on individual animals. The system would use statistical application programs and a report generator. Use of such a system by government agencies and industry encourages standardization of testing protocols, forces standardization of reporting, and incorporates concepts of good laboratory practice.

Of the projects identified to date, Project A (common identification codes) has the highest priority, and Project C (monograph planning and production) the lowest. Priorities need not be invoked, however, unless funding is involved, as different resources are, in general, assigned to each project team.

V. RECOMMENDATIONS

The Information Exchange Work Group recommends that the four agency heads approve these projects and provide resources sufficient to implement them.

The Information Exchange Work Group would provide for interagency liaison and project management of these activities. In order to carry out these responsibilities, the group will need an appropriate level of managerial and operational support. These needs are detailed as project G.

VI. DETAILED INFORMATION EXCHANGE GROUP PROJECT PLANS

Project A: Common Identification Codes

Requirement.—The four agencies presently have information systems that contain chemical-related data. It is difficult, if not impossible, to locate related information in these files due to the lack of common identification codes for specific chemicals, establishment sites, products, and uses.

It is proposed that the four agencies develop common policies for the use of

common identification codes, that implementation plans for these policies be developed jointly, and that these codes be implemented in agency systems.

Outputs.—1. Four-agency policies for the use of common identification codes for chemicals, establishment sites, products, and uses (short range).

2. Coordinated implementation plans for the above policies (medium range).

3. Implementation of common identification codes in the four agencies' systems (long range).

Evaluation.—The success of this project can be measured by the number of eligible agency files for which there are common identification codes, and the degree of use of common codes for file access.

Status and costs, November 1977.—Chemical codes.—The first output of this subproject will be a 4-agency policy designating a chemical coding system of choice to be used in all future chemical data systems (unless a cost/benefit analysis concludes that to do so would be inappropriate), and establishing a review panel to determine, for each existing chemical data system, whether or not a file conversion, to incorporate the code and facilitate data exchange, is necessary. Few resources are required for this policy promulgation beyond staff time already allocated to IRLG activities.

Second, EPA will provide, at no cost to the other agencies, chemical coding services such as codes for newly synthesized chemicals, and for chemical mixtures and the like not now subject to a coding system. This will require no special IRLG funding.

Third, agencies will be required, in pursuance of the policy, to incorporate the chemical code in new chemical data systems. This will likewise require no IRLG funding, and will result in small incremental agency costs for each new data system.

Fourth, the retrofitting of chemical codes to existing data systems, when and if done, would require additional intra-agency staff time (computer programmers) and computer time. Costs per data system will vary greatly with the complexity of the system.

No special interagency funding is projected for any activity related to chemical codes.

Establishment codes.—The second output of this project will be a 4-agency policy designating a coding scheme for establishments (regulated firms, their offices and plants). Activities here will be similar to those performed for chemical codes, except that it is anticipated that coding services will be obtained commercially on a 4-agency basis, and will require interagency funding. The magnitude of this funding will be determined in the first quarter of CY78.

Product codes.—The third output of this project will be a policy, similar to the above, designating a coding scheme for specific regulated commercial products. As in the two previous cases, coding schemes and code maintenance are available commercially. Interagency funding will be required, magnitude to be determined in the first or second quarters of CY78.

Product use codes.—The fourth output of this project will be a hierarchical scheme for coding the uses and functions of products. Complications arise because many products fit into more than one hierarchy, e.g., aerosolized paints. No commercial source of an adequate scheme is known to exist. Development will be based on in-house efforts of EPA (TSCA use coding, now in development), and the CPSC NEISS coding scheme.

Interagency contract support for generation and maintenance of a suitable scheme is anticipated; a cost figure will be estimated in the first or second quarters of CY78.

Project B: Confidential Information

Requirement.—Technical security procedures in the agencies are of varying merit. It is probable that each agency has procedures that are excellent in some ways, flawed in others. Sharing of information on security procedures should result in improved procedures for all four agencies, and uniform procedures should be devised to promote appropriate levels of security at minimum cost. In particular, cumbersome procedures are subject to short-cutting, and so should be avoided.

Each of the four agencies has differing procedures regarding proprietary information, that is, information obtained from industry which is not common knowledge, and which a firm has an interest in keeping from competitors, consumer groups, other Federal agencies, or the public. Much of this information consists of 'trade secrets' apparently prohibited from disclosure under 18 USC 1905. Some examples are:

Formulations of chemical consumer products obtained by CPSC under special order,

Technical proposals received by the agencies in response to RFPs (if claimed to be proprietary by the offeror),

Data on closed or open claims obtained from insurance companies, when these claims relate to regulated products.

The legal definition of 'trade secret' is unclear, and it appears that no Federal employee has ever been prosecuted for release of trade secret data. The definitional issue is now under study by the TSCA Data Policy Committee; a report is expected in October 1977.

Each agency has a set of technical procedures for safeguarding confidential information. These may be formal regulations, published in the FEDERAL REGISTER, or they may be entirely informal, undocumented practices. An agency may have one set of procedures for some types of proprietary data, and another set of procedures for other types.

Outputs.—A set of uniform technical procedures for safeguarding confidential information, to be implemented by each agency (short range).

Evaluation.—By its nature, the results of this project may not be amenable to quantitative evaluation. After a few months of routine operation, however, an *ad hoc* study team (in-house or contracted) could assess the benefits of the project.

Project C: Monograph Planning and Production

Requirement.—Monographs (criteria documents) are substantial literature analyses of a specific topic, most typically on the toxicity of a chemical or class of chemicals, but also occasionally on other hazards such as noise or the physical consequences of fiber inhalation.

Three of the four agencies (EPA, CPSC, FDA) issue contracts to commercial firms for monograph production. OSHA's monographs are developed by NIOSH. The cost of these monographs ranges from about $20,000 in contract costs upwards. In addition to contract costs, agencies contribute considerable resources in expert review of drafts, negotiation with and guidance of contractors, etc.

To some extent, monograph coordination is provided by the Chemical Monograph Referral Center (CHEMRiC), an activity of the DHEW Committee to Coordinate Toxicology and Related Programs, operated by CPSC. CHEMRiC exists to share news of planned, in-preparation, in-draft, and completed monographs leading to reduction in duplication of effort. In the simplest case, agency A decides not to prepare a monograph on chemical C because agency B is already in the process of doing so. B's product can be used by A when completed.

While response to CHEMRiC has shown it to be worthwhile considering the minimal resources expended (0.3 professional man-years per year and $1,500 in computing costs), more substantial monograph coordination among the four agencies could result in substantial savings and better monographs for all. In particular, the incremental costs of adding (e.g.) environmental data to an occupational health monograph are considerably less than the cost of preparing a monograph on the same topic in order to assess its environmental impact. The short-range goal would therefore be to prepare common technical specifications and order of presentation for

monographs on chemical hazards, including environmental, occupational, food, drug, and consumer exposures. The costs of including coverage of each type of exposure would be paid by the cognizant agency, or would be paid out of a joint 4-agency resource pool. (If a chemical is not of interest to one agency, that agency would not be expected to contribute to its costs. This would be the case, e.g., where a chemical has no foreseeable use other than as a pesticide.)

The medium-range goal is to streamline the monograph-acquisition process. Instead of each agency's negotiating its own contracts, identical master contracts would be issued to 2-4 firms, and individual monographs commissioned by each agency by means of task orders and funds transfer to the lead agency (or to the IEWG or IRLG as contracting office). Firms would be selected to receive master contracts by competitive procurement, awards being decided by a panel consisting of one representative from each agency.

Implementation of this plan should not prohibit individual agencies from preparing their own monographs outside the master contract, provided they also participate in the master contract.

Outputs.—Monographs (criteria documents) in a uniform canonical format for all four agencies, but with format-modules designed by each agency, which are included in or excluded from each specific monograph at the option of each agency. Monographs would be placed under uniform bibliographic control and released to the public through appropriate channels (NTIS, GPO, commercial publisher, etc.)

Evaluation.—At the completion of each monograph during the first year of this activity, each agency will assess it on the bases of technical adequacy, suitability to agency needs, and increased or decreased cost over a one-agency activity, and report to IEWG. At the end of the first year the project will be subject to a full-scale four-agency evaluation and modified accordingly.

Project D: Coordination of Reporting Requirements

Requirement.—Agencies impose requirements upon industry to supply data on chemicals they manufacture, import, use, or sell. Each agency's requirements are developed and implemented independently of the others, except for limited coordination provided by the Office of Management and Budget under the provisions of the Federal Reports Act. The General Accounting Office has similar duties relative to the Consumer Product Safety Commission.

The goal of this project is greater uniformity in industry submissions for data, leading to enhanced data sharing capability and to a reduction in the reporting burden placed upon industry. To this end the project will:

Survey existing and proposed reporting requirements in the four agencies and compile an indexed list for the use of management.

Determine which requirements (if any) are duplicative.

Identify those data items required which are of interest to more than one of the four agencies.

Identify non-uniform data requirements that could be made uniform without adverse effect upon any of the agencies, and recommend modifications to ensure uniformity in all instances unless a cost-benefit analysis indicates that in a particular instance such uniformity could not be justified.

The scope of this project is all voluntary or mandatory requirements for reporting or recordkeeping under the cognizance of one or more of the four agencies, where the subject of the report is a chemical substance. All such requirements are in the scope, whether or not there is any concern with the toxic effects of the subject chemicals.

Work will initially focus on requirements of the four agencies, and may then be expanded to cover requirements of other agencies in the Federal Government, with the cooperation of the Office of Management and Budget.

Outputs.—1. Indexed list of current reporting requirements, 2. Recommendations for modifications to specific reporting requirements.

Evaluation.—After modifications have been in effect for one year, an *ad hoc* survey should be made (a) of the agencies to measure the benefits they perceive, and (b) of selected industrial respondants to determine if their reporting burden has been lessened. In addition, users of data in each agency will be surveyed to determine if the changes have made data sharing less costly and less technically difficult.

Project E: Regulated Chemicals System

Requirement.—There is no good centralized source for obtaining all relevant standards and regulations concerning a given chemical. All government agencies and the Interagency Testing Committee that were contacted by MITRE during the course of their study expressed a requirement for such a centralized file.

The Regulated Chemicals System would provide information on standards which have been proposed or promulgated concerning individual chemical substances or classes of chemicals. The system would incorporate occupational standards, transportation, packaging, and labeling requirements, threshold levels, and various procedural regulations which impose industrial reporting requirements with respect to individual chemical substances or classes of substances. State, Federal, and international standards would be included.

The system would be implemented on a data base management system that is publicly available, thereby providing information to manufacturers and processors as to their responsibilities under various legislative authorities. Government agencies, foreign governments, and international organizations would use this system to maintain awareness of proposed and promulgated standards in order to minimize the development of conflicting standards.

Outputs.—1. Feasibility study (short-range), 2. Development of System (medium range), 3. Continued Operation of System (long range).

Evaluation.—The success of this project can be measured by the number of users and the level of their usage.

Project F: Chronic Testing Support System

Requirement.—There is no one system currently available to the four agencies which provides for storing and analyzing chronic toxicity test data interactively. Testing regulations for submission of this data will, by necessity, have to include standard formats for reporting purposes. These formats should be consistent with data submissions required by other government agencies. Industry is apparently agreeable to working out standardized reporting systems for both acute and chronic toxicity testing. This is particularly true for larger firms considering the development of in-house information systems.

The Chronic Testing Support System would provide a software capability and storage and retrieval module for the results of long term chronic toxicity monitoring studies. The system may be used by government agencies in the conduct of long term toxicity testing (e.g., NCTR, NCI), by government agencies who need to review the studies (e.g., by EPA in carrying out its testing responsibilities under TSCA or its other Acts), or by industry when required to conduct chronic tests in response to government regulations. The system would incorporate the requirements of the Carcinogenesis Bioassay Program of the National Cancer Institute and the intergrated laboratory support capability required by the National Center for Toxicological Research. It would support private, independent agency, or industry files with access and update privileges limited to approved users.

The goal of the system is to provide a computer utility for collection, monitoring, evaluating, and reporting of

bioassay information. The system would permit collection of data on chemicals and chemical preparations, experimental procedures and test environment, observation data, and complete pathology reports on individual animals. It would include links to statistical application programs and report generators. Use of such a system by government agencies and industry would encourage standardization of testing protocols, force standardization of reporting, and incorporate concepts of good laboratory practice.

Outputs.—1. Feasibility Study (short range), 2. Development of System (medium range), 3. Continued Operation of System (long range).

Evaluation.—The success of this project can be measured by the number of users and the level of their usage.

Project G: Management and Operational Support

Requirement.—The work of the Information Exchange Work Group requires resources over and above those associated with particular projects. While individual projects could be taxed at a percentage of their resource levels for general support, it is considered perferable to establish a separate project for management and operational support.

Support services are required to enable the IEWG to function optimally. These services include:

Technical and Administrative support.
Secretarial/Clerical support.
Facilities and materials.
As-required consultation on specific topics.

The first three categories of support will be provided by the cognizant agencies; consultation, as and when required, should be provided by when-actually-employed personal services contracts. (It is not anticipated that such contracts will be required before the second half of FY 78.)

Outputs.—The outputs of this project consists of project work plans, ongoing management of the Work Group, planning of the Work Group activities, evaluation of ongoing and completed projects, and reports to IRLG and outside groups.

If a large number (10–20) of projects are eventually underway, resource needs above may need to be doubled.

Evaluation.—Evaluation of the contracts will be made quarterly or more often by the Work Group; evaluation of the management of the Work Group will be made by the IRLG on a continuing basis.

VII. EXAMPLES OF POSSIBLE FUTURE PROJECTS

The table below lists projects identified by the Information Exchange Work Group as worthy of further investigation to determine if they may be suitable for development as project plans by the Work Group in the future. Each project, as appropriate, is divided into short-range, medium-range, and long-range activities.

The table is not intended to include all four-agency information projects which may be considered in the future, but only those suggested by the Work Group members in the brief period since the Work Group was established.

Information Exchange Work Group Examples of Possible Future Projects

Short range	Medium range	Long range
Prepare brief analysis of 4-agency legislation which affects information exchange.	Study feasibility of new legislation to put 4 agencies on the same footing in regard to information collection and exchange.	Draft and propose suitable laws.
Share knowledge of product formulation resources used by each agency, e.g., their own surveys, CTCP, Poisindex.	Share formulations to the extent permitted by law; propose changes in laws.	Establish joint product formulation data base with uniform formats to the extent possible considering the missions of the agencies.
Establish early warning network to promote very rapid sharing of basic information on crisis chemicals.	Continue short-range activities	Continue medium-range activities.
Compile information on various systems for identification of commercial firms (establishments).	Build data base cross-referencing existing systems.	Do.
Prepare and maintain a 4-agency roster of technical information specialists and their areas of expertise.	Hold quarterly meetings/workshops of information specialists to share ideas and approaches.	Establish joint information science service group.
Prepare and maintain a roster of key people and organizations outside the 4 agencies who should be kept informed; meet with them individually as appropriate.	Prepare presentations of outside people and organizations.	Establish advisory committee.
Prepare and maintain a roster of experts in various aspect of toxicology: within the 4 agencies; in other Federal agencies; outside Federal Government.	Consult with toxicologists within the 4 agencies as needed; make individual outside toxicologists available to the agencies via personal services contracts, as needed.	Establish joint toxicology-consultation service.
Using MITRE report as a starting point, share information of data bases among the 4 agencies.	Consider intergrating some data bases as appropriate.	Coordinate data bases for maximum information sharing with minimum incompatabilities.
Share technical library catalogs among the 4 agencies.	Propose nonduplicative acquisition of infrequently used journals; and other types of coordination.	Establish joint technical library system with 4 branch libraries.

DR. PATRICIA BRESLIN,
Chairman, Information Exchange Work Group.

DECEMBER 1, 1977.

REGULATORY DEVELOPMENT WORK PLAN

I. SUMMARY

The Regulatory Development Work Group has agreed on an overall work plan with two preliminary outputs. First, coordinated interagency regulatory action on 28 items/toxic chemicals which are being considered for regulatory action. Second, implementation of an interagency alert system designed to inform the other agencies of an upcoming regulatory action by one of the agencies.

Assuming the two immediate outputs can be accomplished in 1977 the plan calls for work on seven secondary outputs to be initiated in early 1978:

A. Develop a coordinated policy for the funding of public participation in regulation development.

B. Develop procedures for routinely determining which of the statutory authorities implemented by the agencies may be the most appropriate authority to use in response to a given situation.

C. Conduct an analysis of the criteria used by the agencies in evaluating petitions for action and improve procedures used to coordinate responses to petitions by the four agencies.

D. Develop common policies for employees when dealing with regulated industries.

E. Identify and analyze various supplementary approaches to direct regulation such as economic incentives and voluntary industry action.

F. Develop procedures for conducting joint hearings and meetings on common regulatory actions and issues pending before the agencies.

G. Develop a consolidated listing of advisory committees established by the four agencies and consider mechanisms to facilitate the sharing of advisory committees by the agencies.

If the aforementioned regulatory action coordination cannot be accomplished as scheduled, one or more of the 7 secondary activities listed above will be delayed accordingly.

It is recognized that many of the outputs will require the work group to coordinate its activities with the work group formed by the General Counsels of the four agencies.

II. OBJECTIVES

(a) To improve public protection from toxic and hazardous substances.

(b) To provide consistent regulatory policy, share information, and decrease duplication of effort.

(c) To lessen the administrative burden on regulated industries, the public, and the agencies themselves.

III. METHOD OF APPROACH

The function of the Work Group is to produce coordinated action. We will produce an action-tested system rather than general recommendations for change. Any studying of the problem will be by example, rather than in the abstract.

In keeping with this action orientation, the Work Group will immediately inventory pending potential rulemaking actions of the four agencies involving toxic or hazardous substances problems. Appropriate program management will be identified and encouraged to coordinate interagency regulatory development. A coordinated program work plan which reflects the joint and independent regulatory actions will be created for each toxic substance. This will result in early coordination of rulemaking actions among the four agencies in selected areas of concern. It is anticipated that the results of these initial endeavors will be utilized to develop a more general framework for coordinating, to the extent possible, future actions relating to the control of toxic and hazardous substances.

To achieve the goals of continued cooperation and routine coordination among the four agencies, program directors and policy-makers in each of the agencies must be aware of the plans and progress of the Regulatory Development Work Group. Therefore, each representative to the Work Group should take all necessary steps to ensure that his agency's key personnel are consulted about and involved in the activities of the Work Group.

IV. SCOPE OF WORK

A. Initiate Immediate Action by the Four Agencies.

Coordinate rulemaking on 25 items/toxic or hazardous substances which are being considered for regulatory action. This project will include the development of an inventory of current regulatory activities underway in each agency for a wide variety of toxic chemicals such as benzene, arsenic, etc.

Establish an Alert System to inform the other agencies of upcoming regulatory action by one of the agencies. A preliminary system will be in operation by October 1, 1977.

B. Initiate Four-Agency Action by February 1978.

Some outputs to be initiated in this time frame will draw on the experience gained on the "immediate action" items above. The following outputs will focus on actions within existing authorities.

Develop a coordinated policy for the funding of public participation in regulation development.

Develop procedures for determining the most appropriate legislative basis for a rulemaking action by the four agencies. This activity may overlap with the OGC work group activities and possibly might be led by them.

Conduct analysis of criteria for evaluating petitions received by the Agencies to regulate toxic and hazardous chemicals and coordinate action on petitions by the agencies.

Develop common policies for employees when dealing with the regulated industries including policy toward the use of contractors and consultants, if appropriate.

Identify and analyze various supplementary approaches to direct regulation such as the use of economic incentives and voluntary industry action to accomplish public health and environmental objectives.

Develop procedures for conducting joint hearings and meetings on common regulatory actions and issues pending before the agencies.

Develop a consolidated listing of advisory committees used by the four Agencies and consider mechanisms for sharing advisory committees.

C. Initiate Action by July 1978.

Outputs and specific objectives to be initiated in the July 1978 time frame will be identified during the development of the earlier outputs. If appropriate, some outputs may focus on legislative, organizational, or regulatory changes needed to remove constraints to further cooperation among the four agencies.

V. TASKS FOR IMMEDIATE ACTION OUTPUTS

Output A. Coordinate Rulemaking on Selected Chemicals.

Lead Agency—OSHA.
Support Agency—EPA.

1. Preliminary identification of substances on which regulatory action is pending or proposed. 9-26-77
2. Establish a final inventory of chemicals on which multi-agency regulatory actions are pending or proposed. 10-5-77
3. Obtain agencies' inputs on ongoing regulatory activities for designated items/chemicals. 11-1-77
4. Brief lead persons creating coordinated work plans. 11-1-77
5. Contact interagency program personnel for each designated item/toxic substance. 11-15-77
6. Drafts of the coordinated work plans. 12-1-77
7. Final work plans. 12-15-77

Output B. Establish an Alert System.

Lead Agency—CPSC.
Support Agency—FDA.

1. Create interim Alert System procedures for each agency. 9-14-77
2. Initiate test of Alert System. 9-14-77
3. Analyze Alert System test results. 11-23-77
4. Adopt or modify Alert System. 12-20-77

5. On an "as required" basis use Alert System as the initial coordinating and planning point for "crisis chemicals" events, (ongoing).

Output C. Develop Consolidated List of Applicable Advisory Committees and Consider Mechanisms for Sharing Them.

Lead Agency—CPSC.
Support Agency—OSHA.

1. Develop consolidated list of applicable advisory committees in all four agencies. 11-1-77
2. Review membership, scope of activities, etc., of the various committees and determine if any could be utilized by more than one agency. 11-21-77
3. If any sharing is possible, propose optional mechanisms for sharing, including an analysis of costs, policy issues, etc. Recommend whether any sharing is desirable or cost-effective. 12-21-77

VI. TASKS FOR OUTPUTS TO BE INITIATED BY FEBRUARY 1978

D. Develop a Coordinated Policy for Funding Public Participation.

Lead Agency—CPSC.
Support Agency—FDA.

1. Analyze the agencies' existing policies/regulations to determine where differences exist. 11-14-77
2. Identify and analyze basis for differences, i.e., statutory, agency policy. 12-2-77
3. Evaluate operational experience under agencies' programs, in accordance with selected criteria for evaluation. 6-15-78
4. Determine whether identified differences in programs lead, in practice, to inconsistent treatment of individuals in similar situations or in other ways interfere with coordinated Federal approach. 7-15-78
5. Consider ways of reconciling differences to achieve maximum consistency, e.g., establishing uniform policy, seeking legislative action to resolve statutory differences. 8-15-78
6. Implement efforts to achieve maximum consistency. 7-15-78

Output E. Working with the General Counsels, Develop Procedures for Determining the Most Appropriate Legislative Basis for a Rulemaking Action.

Lead Agency—EPA.
Support Agency—CPSC.

1. Analyze the legal bases for action. 1-25-78
2. Establish interim procedures. 2-25-78
3. Develop and analyze alternative procedures. 3-1-78
4. Select most feasible alternative and initiate. 5-24-78

Output F. Conduct Analysis of Criteria for Ranking Petitions for Action and Consider Improved Mechanisms for Coordinating Action in Response to Petitions.

Lead Agency—FDA.
Support Agency—OSHA.

1. Review each agency's current practices and criteria for action. 2-15-78
2. Develop pro/con matrix for criteria and, to the extent possible, establish common criteria.

Output G. Establish Common Policies for Employees When Dealing With the Regulated Industries.

Lead Agency—FDA.
Support Agency—EPA.

1. Review existing policies highlighting overlaps and discrepancies. 2-15-78
2. Identify problems which could be relieved by an improved common policy on conduct. 4-26-78
3. Identify statutory or regulatory constraints. 5-24-78
4. Draft, review, finalize, and implement common policies on conduct. 8-30-78

H. Identify Alternatives and Conduct Analyses of Various Supplementary Approaches to Direct Regulation, Including Economic Incentives.

Lead Agency—EPA.
Support Agency—CPSC.

1. Review and evaluate existing or proposed supplementary approaches. 3-15-78
2. Identify program areas most compatible with nondirect approaches. 4-8-78
3. Draft strategies for prototype non-direct regulatory programs. 5-10-78
4. Initiate prototype programs. 8-30-78
5. Evaluate non-direct supplemental regulatory program and draft appropriate recommendations (ongoing).

I. Establish procedures for Conducting Joint Public Hearings and Meetings.

Lead Agency—OSHA.
Support Agency—FDA.

1. Develop matrix of actions in which public hearings are mandated or policy based. 3-15-78
2. Review regulatory and legislative constraints to joint hearings. 5-10-78
3. Draft proposed procedures for joint hearings and meetings. 7-15-78
4. Finalize procedures and conduct joint hearings and meetings. 9-13-78

VII. RESOURCES AND RESPONSIBILITIES

Lead and primary support agencies are assigned to each of the nine output items as indicated in the Task Descriptions. All agencies will participate in the review of outputs at the regular work group meetings. The establishment of additional "Sub-Work Groups" for each task was considered but rejected because of added bureaucratic and management problems.

Work Group representatives are responsible for ensuring adequate resource commitments and timely completion of tasks assigned to their respective agencies. From time to time, other Work Group members may be called upon to support a particular task, and the work group members have agreed to respond positively to any such requests. Overall, the tasks will be carried out by the work group as a whole, under the leadership of the designated agency.

MR. HENRY E. BEAL,
Chairman, Regulatory Development Work Group.

NOVEMBER 30, 1977.

RESEARCH PLANNING WORK PLAN OBJECTIVES AND GOALS

Regulatory decisions on toxic substances rest on a foundation of technical information. Since many such substances are of common interest to one or more of our four agencies, there are obvious advantages to the joint acquisition and usage of such data through the coordination of toxicity-related research of mutual interest.

In keeping with the ACTION NOW philosophy of the IRLG, the Research Planning Work Group has identified three major goals for immediate implementation:

A. Document and coordinate existing (planned for FY 78 and 79) projects in the four agencies to eliminate undesirable duplication, maximize effectiveness and identify gaps in needed research.

B. Jointly plan and coordinate budgets for selected mutual interest programs/initiatives for inclusion in the President's FY 80 Budget Submission to Congress.

C. Develop a comprehensive action plan for more effectively utilizing nonregulatory research programs in regulatory decisionmaking.

The subordinate tasks required to achieve these goals are discussed in the following text and implementation schedule.

GOAL A. INVENTORY AND COORDINATION OF EXISTING RESEARCH

Task 1.—*Exchange Complete Listings of Intra-Extramural Research Projects*—The four agencies will provide a complete, compatible listing of all current intra and extramural research (as well as that proposed for FY 79). The Work Group will initiate this task immediately using a standardized format. As a minimum, this would include the project title, a brief narrative giving the objectives and the anticipated results and the level of effort. A mechanism will be established for the continuous updating of the joint compendium.

Task 2.—*Preparation of Report on Major Areas of Overlap and/or Gaps in Research, with Recommendations for Action*—Upon completion of the research inventory, the Work Group

staff will begin the actual process of coordination by analyzing existing projects to determine:

(a) Areas of common interest;

(b) Current levels of effort;

(c) Obvious redundancies in research; and

(d) Apparent gaps or deficiencies.

Emphasis will be placed upon the 12 research needs which have been identified as high priority areas by the agency heads. For these priority areas a separate report will be developed to identify the type and level of existing effort both within and outside the agencies.

On the basis of this analysis, the Work Group will make recommendations for immediate actions in the form of Program and Budget redirection, including: suggestions for future joint funding, designation of a "lead" agency and the development of collaborative protocols for actual research investigations.

Task 3.—*Implementation of Approved Program/Budget Actions*—Upon approval by the agency heads, the Work Group will immediately take the necessary, coordinated steps to insure the appropriate reprogramming of agency efforts (Task 2).

This task will help demonstrate the feasibility of coordinated research efforts between the four agencies.

GOAL B. JOINT INITIATIVES FOR PRESIDENT'S FY 80 BUDGET SUBMISSION

The initial research inventory and the ensuing recommendations affecting the FY 79 Budget (Goal A) are designed to initiate substantial interagency coordination at the earliest possible time. This second level of initiatives (Goal B) is designed to establish a permanent process for deepening and expanding such coordination.

Task 1.—*Develop 4-Agency Coordination Budget Action Plan*—A permanent Implementation Committee will be formed, consisting of the present Work Group, with the responsibility to provide direct input to agency representatives involved in the budget and planning processes.

Task 2.—*Analysis of Areas of Mutual Interest and Recommendations for Joint Planning/Budget Initiatives*—Areas of mutual interest having been previously identified (Goal A, Task 2), *ad hoc* technical analysis committees, consisting of designated bench scientists of the four agencies, will be formed for exchange of technical information, discussion and recommendations to the Implementation Committee.

This will insure that the technical insight of those who are most knowledgeable on the subject matter will be integrated into the planning and budget processes.

The permanent Implementation Committee will analyze these recommendations, establish the priorities for research funding and make recommendations for coordination and redirection to the four agency heads (as part of Task 3).

Task 3.—*Joint Testimony Before OMB and Congress Relating to Mutual Research Initiatives*—This planning and budget process should result in technically sound Mutual Research Initiatives, and will provide an unprecedented basis for the presentation of budget testimony. The process will insure an absence of redundancy, will provide programs that have mutual interest to several agencies rather than competitive efforts, and allow agency heads to testify in a collaborative manner.

GOAL C. REGULATORY V. NON-REGULATORY RESEARCH ACTION PLAN

Regulatory research depends to a large degree on the findings of earlier basic, non-regulatory research. Ideally, coordinated basic R&D should provide the base from which an expedient transition can be made into the studies that may be required to implement regulations. The Action Plan is designed to achieve the necessary coordination. Subsequently updating of this plan in line with new priorities and program efforts will assure that future needs can be projected and completed as required in the regulatory decisionmaking process.

Task 1.—*Request Project Listing from Supporting Agencies/Institutes*—The Work Group will initially acquire from appropriate non-regulatory agencies inventories of all current or projected research in areas of common interest to the four agencies. Agencies to be included are:

(a) National Institute of Environmental Health Sciences.

(b) National Cancer Institute.

(c) Other National Institutes of Health.

(d) National Institute for Occupational Safety and Health.

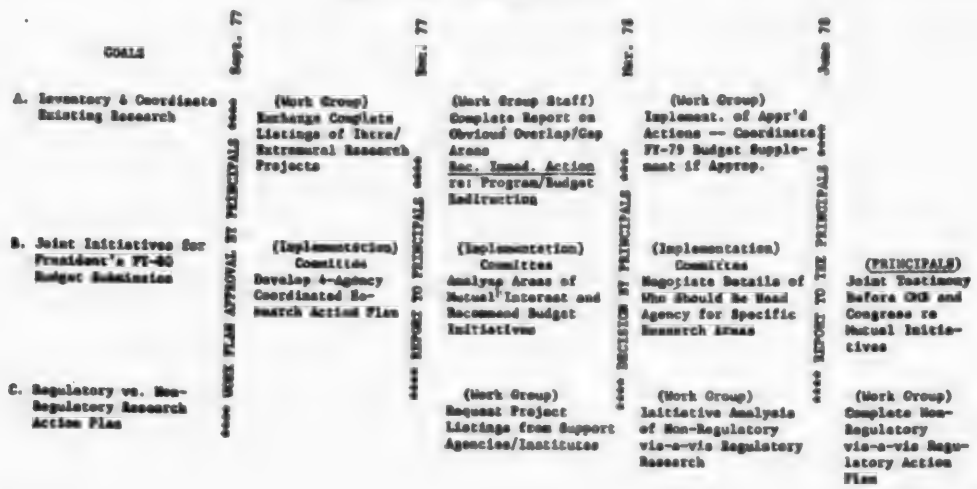
(e) Communicable Disease Center.

(f) National Oceanographic and Atmospheric Administration.

Task 2.—*Initiate Analysis of Non-Regulatory vis-a-vis Regulatory Research*—The Work Group will analyze the preceding inventory to determine subjects of priority interest to the four agencies.

Task 3.—*Complete Non-Regulatory vis-a-vis Regulatory Research Action Plan*—Based on the preceding analysis, the Work Group will recommend to the four agency heads a plan for coordination or new initiatives required for regulatory decisionmaking.

RESEARCH PLANNING TASKS/MILESTONES


GOALS
Sept. 77
Dec. 77
Mar. 78
June 78
A. Inventory & Coordinate Existing Research
(Work Group) Exchange Complete Listings of Intra/Extramural Research Projects
(Work Group Staff) Complete Report on Obvious Overlap/Gap Areas
Rec. Immed. Action re: Program/Budget Redirection
(Work Group) Implement. of Appr'd Actions -- Coordinate FY-79 Budget Supplement if Approp.
B. Joint Initiatives for President's FY-80 Budget Submission
(Implementation) Committee Develop 4-Agency Coordinated Research Action Plan
(Implementation) Committee Analyze Areas of Mutual Interest and Recommend Budget Initiatives
(Implementation) Committee Negotiate Details of Who Should Be Head Agency for Specific Research Areas
(PRINCIPALS) Joint Testimony Before OMB and Congress re Mutual Initiatives
C. Regulatory vs. Non-Regulatory Research Action Plan
(Work Group) Request Project Listings from Support Agencies/Institutes
(Work Group) Initiative Analysis of Non-Regulatory vis-a-vis Regulatory Research
(Work Group) Complete Non-Regulatory vis-a-vis Regulatory Action Plan
WORK PLAN APPROVAL BY PRINCIPALS
REPORT TO PRINCIPALS
DECISION BY PRINCIPALS
REPORT TO THE PRINCIPALS

DECEMBER 9, 1977.

DR. ROBERT L. ELDER,
Chairman, Research Planning Work Group.

RISK ASSESSMENT WORK PLAN

I. SCOPE AND JUSTIFICATION

A. *Broad Objective.*—The Risk Assessment Work Group will develop procedures and criteria that can be uniformly applied by the four agencies for purposes of characterizing and quantifying human health risks associated with certain chemicals.

B. *General Background.*—

1. *Introduction*—A common objective of the four agencies is the assessment of human health risks associated with chemicals, devices, consumer goods, etc. to which the population of the United States is exposed in a variety of ways. In general the goals of risk assessment are to characterize the types of health hazards that may result from such exposures and to quantify the expected risks. For the present, the Work Group intends only to treat the problems associated with health risks due to chemicals. It is in this area that the greatest commonality of purpose exists among the agencies. Moreover, it is the area in which the greatest confusion now exists, not only among the public, but also within the regulated industry. It is also the subject presenting one of the greatest opportunity for successful achievement of the broad objectives of the IRLG.

2. *The Scientific Problem*—Characterizing and quantifying health risks are scientific tasks. The data necessary to accomplish such tasks derive from toxicity testing and/or epidemiological studies. Also needed is information on the known or expected level of human exposure to the chemicals of concern. Other IRLG Work Groups are developing approaches to the proper collection of such information. The Risk Assessment Work Group will develop procedures to treat the data for purposes of assessing human risk.

Because of serious gaps in scientific knowledge, there are often alternative and conflicting views of the risks associated with chemicals to which people can be exposed. The Risk Assessment Work Group will examine the available scientific tools used in such assessments and select for use by the four agencies those currently having the strongest experimental and theoretical support. Unless selections of these types can be made and agreed upon, conflicting views of risk will continue to cloud regulatory decision-making.

3. *Role of the Policy-Maker*—Whether a particular type or level of risk may have to be accepted in certain circumstances is a policy decision, but this issue should not become entangled with the scientific problem of risk measurement. The Working Group will restrict its task solely to the development of procedures for making risk assessments and will stop short of making statements regarding the balancing of risks and benefits or suggesting the appropriate regulatory responses for particular types and levels.

4. *Need for Uniform Procedures and Criteria*—The public and the regulated industry are ill-served when the agencies assess risk in different ways. Policy decisions made by the four agencies on the degree of acceptable risk in different circumstances create substantial confusion (in part brought about by differences in legal mandate and interpretation) and this confusion should not be compounded by differences in approach to the scientific assessment of risk.

5. *Task of the Work Group*—An objective of the Work Group might be the development of systems to insure that the agencies routinely work together to conduct risk assessments on specific substances of mutual interest. However, the Work Group holds that such an objective is far less important than the broader one of developing and selecting general procedures and criteria for risk assessment that can be uniformally applied to all chemicals regulated by the agencies, including those substances for which only one agency is responsible.

Until the rules for risk assessment are clearly laid out and agreed upon, efforts to reach a consensus on the type and degree of risk associated with specific substances of mutual concern will in many instances be thwarted. Furthermore, in the absence of uniform criteria and procedures, the risks associated with chemicals that are the responsibility of only one agency will continue to be estimated in a different manner than those associated with chemicals regulated only by a second agency. This undesirable situation will not be remedied if the task of the Work Group is limited to the joint conduct of risk assessments on substances of mutual interest.

6. *Output of the Work Group*—Several projects are envisioned (Section IV). Out of each will come a document detailing a set of procedures and criteria that can be adopted by each agency as acceptable for assessing risk. After appropriate internal review, these documents will be jointly published in some form and will become part of the scientific operations of the agencies.

II. CURRENT STATUS

There has never been a joint, in-depth examination of the various approaches to risk assessment now in use by the four agencies. The Work Group will need some time to catalogue current procedures and criteria, to identify differences and the reasons for them, and to decide on action necessary for the resolution of differences. Further complicating the task will be the almost certain discovery of a complete lack of rational criteria and procedures for assessing some types of risk.

III. GENERAL APPROACH OF WORK GROUP

Listed in Section IV are specific projects, each of which is an integral component of the task of risk assessment. Although the individual projects or subprojects may require somewhat different approaches, the following steps serve as a general guide to the activities of the Work Group:

Step 1: Develop a complete statement of the problem.

Step 2: Catalogue present approaches of the four agencies and differences in approach.

Step 3: Determine if any of the differences are necessitated by differences in law.

Step 4: Study approaches in use and others available.

Step 5: Select, where possible, a common approach, and prepare a document detailing the reasons for the choice. Where a common approach is not possible, explain why. This document will also provide instructions for the conduct of assessments and on the proper use of such assessments in regulatory decision-making.

Step 6: Develop a plan, where necessary, for continued study and evaluation of alternative approaches.

Step 7: Announce publicly and jointly the selected approach and reasons for the selection; where a

common approach cannot be used, explain why.

Step 8: Incorporate the selected approach into the review and evaluation operations of each agency.

Step 9: Provide for continuous, joint review of specific problems encountered as the selected approach is applied.

The first six steps are activities of the Work Group alone. The last three steps cannot be carried out without broader agency cooperation.

IV. PROPOSED PROJECTS OF THE RISK ASSESSMENT WORK GROUP

The Work Group intends to accomplish its objective by first undertaking the following project:

Project RA1—Procedures and Criteria for Assessing Health Risks Associated With Carcinogens

Of the several types of health risk projects that could be undertaken by the Work Group, a project on cancer risk assessment presents the highest probability for relatively short-term, successful accomplishment. A good portion of the necessary background documentation and study has been done, and the remaining tasks of bringing together the necessary information and making selections among the available approaches to carcinogenesis risk assessment should prove relatively straightforward.

Following upon successful completion of Project RA1, the Work Group, guided by the experience gained, similarly intends to treat other types of health risks that may be associated with chemicals.

V. ACCOMPLISHMENT OF OBJECTIVES

Outlined below are the factors to be considered and resolved to complete RA1 (Carcinogenesis Risk), and the resources necessary for each step.

Project RA1—Procedures and Criteria for Assessing Health Risks Associated With Carcinogens

A. *Final Objective and Outcome.*—Incorporation of the selected procedures and criteria into the review and evaluation activities of the agencies. Risks associated with all chemicals capable of inducing cancer will be assessed in the same way.

B. *General Approach.*—As shown under Section III.

C. *Factors Involved in Risk Assessment.*—1. Biological Information Relating to Carcinogenesis.

2. Information on Extent, Level, and Type of Human Exposure.

3. Procedures for Quantifying Carcinogenic Risk.

The Work Group will consider the various ways in which each of the above factors in the risk assessment equation are now being treated (if at all) by the agencies, examine other possible approaches, and finally settle on an approach to be adopted by the four agencies. If a common approach cannot be adopted, the reasons why will be detailed.

Work on the three factors can proceed concurrently rather than sequentially, since different scientific skills are required for each.

D. *Specific Issues to be Considered and Resolved.—RA1.1: Information Relating to Carcinogenesis.*—Output: Criteria for Classifying a Chemical as a Carcinogen.

Tasks.—Since the general criteria for assessing the evidence of carcinogenicity adopted by the NCI, EPA guidelines for assessing risks from suspected carcinogens, and the recently proposed OSHA criteria for assessing carcinogenic risks are in substantial agreement, the sub-committee has agreed to use these documents as a departure point in developing a consolidated approach to evaluating data as evidence that an agent is likely to propose a carcinogenic health risk.

As a first task, the subgroup will address the significance of various types of data including those from epidemiologic studies, animal bioassay studies, short term, *in vitro* tests, chemical structure, metabolic data, etc. Statistical procedures for treating animal data to establish significance will also be detailed.

The sub-committee will identify those problems attendant to the evaluation of data as evidence that an agent poses a carcinogenic risk and, where guidance is not available, will make recommendations for resolving difficult issues. A particularly troublesome issue to be treated is that of deciding the extent of testing required before a chemical can be classified as posing *no* carcinogenic threat. This matter is important for substances (e.g., food additives) requiring pre-market clearance.

Since each Agency will be reviewing the same data base with regard to the regulation of a particular agent as a suspected human carcinogen, the subcommittee will investigate options for sharing risk assessments or performing joint risk assessments where feasible.

Resources.—The sub-committee requires the participation of at least the following individuals:

R. Albert, M.D.—EPA.
E. Anderson, Ph. D.—EPA.
R. Bates, M.D.—FDA.
J. Rodricks, Ph. D.—FDA.
E. Bingham, Ph. D.—OSHA.
A. Keller, Esq.—OSHA.
J. Wagoner, Ph. D.—OSHA.
S. Bayard, Sc.D.—CPSC.

Specialized problem areas (e.g., hormonal carcinogenesis) may require that the Work Group consult individuals at NCI, NIEHS, NCTR, etc.

Schedule.—The first task will be developed in draft by mid-April, 1978. The sub-committee anticipates sharing various drafts of the general principles with internal committees for each of the four Agencies so that the draft available in mid-April will have the general approval of the four Agencies and can then be sent to each Agency's Advisory Committee and other Federal Agencies for review. By 30 April, a draft document should be available for a comment period. (See Overall Timetable, Section VI.)

The second task will be developed simultaneously with the first and will be completed by mid-June.

The third task will be developed simultaneously with tasks 1 and 2 and will be a part of the final package for consideration by the four Agencies by mid-June.

Constraints.—No serious constraints are envisioned.

RA1.2—Human Exposure

Output: Procedures for treating available data to estimate type, level, and extent of human exposure to suspect chemicals.

Task.—The subgroup will survey approaches used by the four agencies. Thereafter areas needing further elaboration will be defined and final procedures developed. Detailed listings of population subgroups of concern will be described; procedures will be developed so that the special subgroups of concern to the different agencies will be treated similarly, when possible.

Where monitoring data are available for use in exposure estimates the character and quality of the data will need to be defined. In the absence of monitoring data the types of information to be used for estimating exposure are primarily related to the manner of use of a chemical and associated consumption levels either estimated or known. A mass-balance approach, which includes details on pathways, release points, transport through media and fate may have to be developed. An inventory of the types of measurements taken to describe human exposure levels is needed.

Resources.—The subject of human exposure is not distinctly defined in its use by the regulatory agencies. It has been difficult to identify individuals at this point who can help. Thus, the subcommittee members will identify individuals who can contribute as the survey tasks progress. Initially, at least the following individuals will be involved:

Dr. F. Kover—EPA.
Ms. F. Ryer—OSHA.
Dr. R. Woitman—CPSC.
Dr. J. Modderman—FDA.

Schedule.—The surveys can be completed by the end of 1977 (the calendar year) so that in January an evaluation can be made of the collected information. A new work plan will be drawn up, as appropriate, as well as a

brief report on survey findings and conclusions of the analysis. A draft report will be available by April, 1978.

Constraints.—No serious constraints anticipated.

RA1.3—Procedures for Quantifying Carcinogenic Risk

Output: Procedures for treating available dose-response relationships to estimate risk at expected or known levels of human exposure.

Task.—The subgroup will survey the risk estimation procedures currently in use by the agencies. Reasons for the use of specific procedures, including relevant legal matters, will be detailed.

An updated review and discussion of all current mathematical models will be undertaken, including consideration of time-to-tumor analyses, as a preface to the final selection of a model(s). The final document will include procedures for combining data from several experiments, use of human data, and modifications based on metabolic and kinetic data.

Resources.—The subgroup requires participation of at least the following individuals:

Dr. D. Gaylor—FDA.
Dr. S. Bayard—CPSC.
Ms. A. Barton—EPA.
Mr. E. Allera—FDA.
Dr. D. Hoel—NIEHS.
Dr. C. Brown—NCI.
Dr. J. Wagoner—OSHA.

Schedule.—The agency survey phase of the work will be completed by the end of 1977. The review and critique phase will be completed in January 1978. A draft final report will be ready by April 1978.

Constraints.—No serious constraints are envisioned.

VI. OVERALL TIMETABLE FOR RA.1

A first draft of the essential features of each of the three components will be prepared by March 1, 1978.

A second draft, to include new material considered and developed in March 1978, will be prepared by April 30, 1978.

Agency review will take place during May and June 1978.

A final set of criteria and procedures, integrating the three components (RA.1.1, RA1.2, RA1.3), will be prepared by October 1, 1978.

VII. OTHER ACTIVITIES

1. An FDA-sponsored symposium "Benefit-Risk Decisions and Public Health," to be held February 15-17, 1978, in Colorado Springs, will deal with issues directly relevant to the Work Group's activities. Work Group members plan to attend and to incorporate useful information or ideas into the group's final document.

The newly-formed Toxic Substances Strategy Committee of the Council on Environmental Quality (CEQ) plans to produce a set of general (and eventually, specific) principles regarding carcinogenesis risk assessment. The IRLG will closely align its activities with that of the CEQ.

DR. JOSEPH V. RODRICKS,
Chairman,
Risk Assessment Work Group.

NOVEMBER 15, 1977.

TESTING STANDARDS AND GUIDELINES WORK PLAN

I. WORK GROUP OPERATING PRINCIPLES

The Work Group has agreed that the following tenets will be applied as it proceeds with the task to develop testing guidelines, criteria for interpretations, quality assurance procedures, and other policies relating to the testing of toxic and hazardous substances.

A. Decisions will be made by consensus. Consensus here means collective agreement. Therefore, it is understood that any document recommended by this work group to the IRLG is acceptable to each and every work group member.

B. Guidelines will be developed for conducting studies that are mutually acceptable and useful, but each agency must determine how it will use the data generated by those studies.

C. Outside guidance will be solicited when appropriate, but formal advisory groups will not be established.

The group recognizes the value of balanced, widespread input and will seek to establish contacts with experts from industry, academia, and public interest groups.

It also recognizes that guidelines agreed upon by these four agencies may influence international standards for toxicology testing. Consequently, the group will attempt to coordinate the development of these guidelines with appropriate international organizations such as OECD and WHO.

D. The activities of the group should neither impair nor impede essential rulemaking by individual agencies. Attempts will be made to complement current agency activities and to incorporate the results of ongoing agency efforts into the final Work Group product.

E. The Work Group will be kept small, and it will form from its present membership a subgroup to develop standard guidlines for tests in the ecological and environmental areas. The Work Group and the subgroup will draw on the expertise of other staff members as needed to gain overall perspective and to insure completeness.

F. To keep the public informed, the Work Group will publish in the FEDERAL REGISTER the guidelines as they are developed as well as notices of public Work Group meetings and public forums.

II. GOALS

Definition of terms: Short Term Goals—Action could be taken within 6 months. Intermediate Goals—Action would require 6 months to a year to accomplish. Long Term Goals—Action would require over one year to accomplish.

The Work Group anticipates that some of the short term and intermediate goals may develop into longer term goals. In such cases, the limitations will be identified and dealt with as they become evident.

A. Short Term Goals

1. Review documents currently available and used by the agencies as guidelines for testing or Good Laboratory Practices.

2. Develop working definitions for tests the agencies now require in order to use a common vocabulary in the establishment of common guidelines.

3. Standardize guidelines for:

(a) Acute tests related to assessment of health effects:

(1) Dermal, (2) Inhalation, (3) Ocular, (4) Oral administration.

(b) Tests related to assessment of ecological and environmental fate and effects:

(1) Species for use in toxicity bioassays, (2) Fish toxicity—acute toxicity, (3) Bird toxicity—acute toxicity in seed-eating birds, (4) Phytotoxicity—foliar toxicity; algal assay, (5) Aquatic invertebrate toxicity—*Daphnia* acute and chronic toxicity; oyster/clam shell deposition growth assay; and oyster larvae acute toxicity, (6) Microbial effects testing—growth inhibition of bacteria, fungi and actinomycetes; laboratory scale activated sludge communities, (7) Fish bioconcentration test, (8) Vapor pressure, (9) Water solubility, (10) Hydrolysis rates (aqueous systems only), (11) Adsorption/Desorption, (12) Octanol/Water partition coefficient.

4. Consider for adoption the FDA Good Laboratory Practices for related toxicology studies.

5. Consider for adoption the PHS Safe Practices for the Handling of Carcinogens.

6. Consider for adoption the PHS Guidelines for the Protection of Human Subjects in Toxicity Tests.

B. *Intermediate Term goals*

Standardize guidelines for:

1. Tests related to assessment of health effects:

(a) Subchronic studies, (b) Chronic toxicity, (c) Carcinogenicity, (d) Teratogenicity, (e) Reproduction.

2. Tests related to assessment of environmental hazard:

(a) Fish and frog egg-larval subacute toxicity, (b) Waterfowl acute toxicity, (c) Semi-aquatic invertebrate toxicity—midge subacute toxicity, (d) Terrestrial invertebrate toxicity—honeybee acute toxicity, (e) Microbial degradation of chemicals—non-enriched mixed cultures dervied from activated

sludge, soil, or stocks of cultured organisms, (f) Microbial metabolic functions—nitrogen fixation; nitrification, denitrification; cellulose, starch, and protein degradation, (g) Phytotoxicity—seed germination; growth assays; duckweed toxicity, (h) Hydrolysis rates (soil systems), (i) Photolysis rates, (j) Leaching rates, (k) Vapor loss from leaf, soil, and water surfaces.

C. *Long Term Goals*

1. Tests related to assessment of health effects:

(a) Mutagenicity tests, (b) Behavioral studies, (c) Neurological tests, (d) Short term *in vitro* tests.

2. Tests related to assessment of environmental hazard:

(a) Aquatic invertebrate toxicity—acute and chronic toxicity in *Gammarus*, mysid and penaeid shrimp, crayfish, bivalves, (b) Fish toxicity—egg to egg chronic toxicity, (c) Microcosm protocol for measuring ecosystem-level effects.

3. If necessary, propose legislative changes needed to permit development of additional uniform guidelines.

4. Data submission and review formats (in conjunction with the Data Integration Subgroup of the Information Exchange Work Group).

DR. JAMES R. BEALL,
Chairman, Testing Standards and Guidelines Work Group.

NOVEMBER 18, 1977.

PUBLIC MEETINGS

Pursuant to the provisions of the Interagency Agreement (42 FR 54856, October 11, 1977), which established the Interagency Regulatory Liaison Group, notice is hereby given that the following Work Groups will hold public meetings at the dates, times and places listed. (The Testing Standards and Guidelines Work Group held a public meeting on December 14, 1977.)

COMPLIANCE AND ENFORCEMENT WORK GROUP

Monday, March 6, 1978, 10 a.m. until 12 noon, FDA, 200 C Street SW., room 1409, Washington, D.C. 20201.

EDUCATION AND COMMUNICATIONS WORK GROUP

Thursday, March 2, 1978, 2 p.m. until 4 p.m., EPA, 401 M Street SW., room 2117/2123, Washington, D.C. 20460.

EPIDEMIOLOGY WORK GROUP

Friday, March 3, 1978, 10 a.m. until 12 noon, EPA, 401 M Street SW., room 3906/3908, Washington, D.C. 20460.

INFORMATION EXCHANGE WORK GROUP

Friday, March 3, 1978, 10 a.m. until 12 noon, EPA, 401 M Street SW., room 2117/2123, Washington, D.C. 20460.

REGULATORY DEVELOPMENT WORK GROUP

Thursday, March 2, 1978, 2 p.m. until 4 p.m, EPA, 401 M Street SW., room 3906/3908, Washington, D.C. 20460.

RESEARCH PLANNING WORK GROUP

Monday, March 6, 1978, 10 a.m. until 12 noon, FDA, 200 C Street SW., room 1813, Washington, D.C. 20201.

RISK ASSESSMENT WORK GROUP

Friday, March 3, 1978, 2 p.m. until 4 p.m., EPA, 401 M Street SW., room 3906/3908, Washington, D.C. 20460.

Purpose: Each Work Group will present updated information about the activities, goals, and procedures, as outlined in their work plans. The Work Groups will invite questions and comments from the public.

For further information, contact Ms. Susan Guenette, IRLG Executive Assistant, at 301-492-6731 or address correspondence to Ms. Susan Guenette, IRLG Executive Assistant, Consumer Product Safety Commission, 5401 Westbard Avenue, Room 450, Bethesda, Md. 20207

COLIN B. CHURCH,
Chairman, Interagency Regulatory Liaison Group.

FEBRUARY 3, 1978.

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